OPERATING INSTRUCTIONS

LIFEPAK® 500

automated external defibrillator

IMPORTANT

Federal (USA) law restricts this device to sale by or on the order of a physician.

This instrument is to be used by authorized personnel only.

Device Tracking

(USA only, including US government-owned units)

The Food and Drug Administration requires defibrillator manufacturers and distributors to track the location of their defibrillators. If your defibrillator has been sold, donated, lost, stolen, exported, or destroyed, or if it was not obtained directly from Medtronic Physio-Control Corp., please notify Medtronic Physio-Control Corp. at 1.800.442.1142, extension 4530.

Responsibility for Information

It is the responsibility of our customers to ensure that the appropriate person(s) within their organization have access to this information, including general safety information provided in Section 1.

Revision History

These operating instructions describe LIFEPAK 500 devices with the monophasic defibrillation waveform (software version 4.5 or later) or the biphasic defibrillation waveform (software version 2.0 or later). Older deices may not have all the features described in this manual.

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PN 3005338-005

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ABOUT DEFIBRILLATION

Defibrillation is a recognized means of terminating certain potentially fatal arrhythmias. A direct current defibrillator applies a brief, high-energy pulse of electricity to the heart muscle. The LIFEPAK® 500 automated external defibrillator (AED) delivers this energy through disposable defibrillation electrodes applied to the patient's chest.

Defibrillation is only one aspect of the medical care required to resuscitate a patient with a shockable ECG rhythm. Depending on the situation, other supportive measures may include:

- Cardiopulmonary resuscitation (CPR)
- Administration of supplemental oxygen
- Drug therapy

It is recognized that successful resuscitation is related to the length of time between the onset of a heart rhythm that does not circulate blood (ventricular fibrillation, pulseless ventricular tachycardia) and defibrillation. The American Heart Association has identified the following as critical links in the chain of survival from cardiac arrest:

- Early access
- Early CPR by first responders or bystanders
- Early defibrillation
- Early advanced life support

The physiological state of the patient may affect the likelihood of successful defibrillation. Thus, failure to resuscitate a patient is not a reliable indicator of defibrillator performance. Often, patients will exhibit a muscular response (such as jumping or twitching) during energy transfer. The absence of such a response is not a reliable indicator of actual energy delivery or device performance.

OPERATOR CONSIDERATIONS

The LIFEPAK 500 AED is a semi-automatic defibrillator that uses a patented Shock Advisory System™. This software algorithm analyzes the patient's electrocardiographic (ECG) rhythm and indicates whether or not it detects a shockable rhythm. The LIFEPAK 500 AED requires operator interaction in order to defibrillate the patient.

The LIFEPAK 500 AED is intended for use by personnel who are authorized by a physician/medical director and have, at a minimum, the following skills and training:

- CPR training
- AED training equivalent to that recommended by the American Heart Association
- Training in the use of the LIFEPAK 500 AED

INDICATIONS FOR USE

The LIFEPAK 500 AED is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing spontaneously before the device is used to analyze the patient's ECG rhythm. This device is not intended for use on children less than eight years of age.

The LIFEPAK 500 AED is intended for use in the hospital and out-of-hospital environments including aircraft (see Specifications, page 5-17).

FEATURES OF THE LIFEPAK 500 AUTOMATED EXTERNAL DEFIBRILLATOR

The optional and configurable features of the LIFEPAK 500 AED are designed to meet a variety of protocol needs. Authorized operators of this AED should always use the AED in accordance with local protocols.

Defibrillation Waveform

The LIFEPAK 500 AED is available with one of two defibrillation waveforms: monophasic or biphasic. For a description of each defibrillation waveform, refer to pages 5-15 and 5-18. The LIFEPAK 500 AED control and display functions are the same for either defibrillation waveform.

Defibrillation Electrodes

The AED uses disposable QUIK-COMBO™ pacing/defibrillation/ECG electrodes, with or without the REDI-PAK™ preconnect system, and FAST-PATCH® disposable defibrillation/ECG electrodes. The use of these electrodes allows rapid transfer of care to other devices that also use the same type of Medtronic Physio-Control electrodes.

Automated Operation

The operator controls AED operation with two or three top-panel buttons (ON/OFF, ANALYZE [optional], and SHOCK). For LIFEPAK 500 AEDs that do not have an ANALYZE button, the AED operates in AUTO ANALYZE 2 mode (see page 2-8).

The AED guides the operator through operating procedures with a combination of:

- Voice prompts
- Tones
- Flashing LEDs
- Screen messages

The screen messages appear on a two-line liquid crystal display (LCD). Other LCD information includes:

- Real-time clock
- Cumulative shock counter
- Status and service messages
- CPR countdown timer

Continuous Monitoring

The LIFEPAK 500 AED operates in two modes: ECG analysis and Continuous Patient Surveillance System (CPSS). During analysis, the AED indicates if it detects a shockable or nonshockable rhythm. The CPSS, which is active when the AED is not performing an analysis, automatically monitors for a potentially shockable rhythm.

Motion Detection

The LIFEPAK 500 AED includes a patented system that detects motion. When motion that could distort the ECG rhythm occurs, the ECG data is automatically excluded from analysis by the motion detection system.

Data Management

The LIFEPAK 500 AED digitally records patient data, including ECG rhythm and delivered shocks. A digital audio recording of scene activity is available as an option. Recorded data may be transferred by direct connection to a printer or computer or by a modem to a remote computer. Three optional, Microsoft® Windows®-compatible data management software programs are available. The Data Transfer 500™ program transfers, stores, and prints AED reports. The QUIK-VIEW™ 500 data review program includes all of the Data Transfer 500 functions and the capability to review ECG and audio data on a computer. The CODE-STAT™ Suite data management system provides comprehensive and varied data storage, review, and reporting capabilities for quality assessment and system performance analysis.

Battery Options

A rechargeable sealed lead-acid battery or a nonrechargeable lithium battery provides power to the AED. The rechargeable battery requires periodic recharging by an external battery charger.

Automatic Self-Test

The AED performs an automatic self-test every 24 hours and every time you turn on the AED. This feature tests the most important circuitry in the device to give the user a high degree of confidence that the AED is ready for use.

Readiness Display

The LIFEPAK 500 AED with the biphasic waveform includes a Readiness Display on the device's handle that can be seen at all times. OK displays if the automatic self-test is completed successfully. If the self-test detects that service is required or if the device detects that the battery needs immediate replacement, the OK indicator disappears and a service and/or battery indicator appear(s).

Customized Setup

AED operation may be customized by accessing a setup mode. Definable operating features include the modem phone number, the time interval allowed for CPR, and other features. Refer to the LIFEPAK 500 automated external defibrillator Setup Instructions (PN 3012275) for more information about customized setup options.

Once you have customized the setup, the TRANSFER SETUP feature enables you to quickly transfer the setup to other LIFEPAK 500 AEDs.

Optional Accessories

An optional carrying case helps to protect the AED and provides a pouch to store electrodes. Use the Physio-Control LIFEPAK AED TRAINER to train operators to use the LIFEPAK 500 AED.

TEXT CONVENTIONS

Throughout this manual, special text characters are used to indicate labels, LCD messages, and voice prompts:

Operating control labels:	CAPITAL LETTERS such as ON/OFF and SHOCK.
LCD messages:	CAPITAL LETTERS such as CONNECT ELECTRODES.
Voice prompts:	*CAPITAL ITALICIZED LETTERS* such as *PUSH ANALYZE*.

CE 0123

DECLARATION OF CONFORMITY according to EN 45014

Medtronic PHYSIO-CONTROL

Manufacturer's Name:	**Medtronic Physio-Control Corp.**
Manufacturer's Address:	**11811 Willows Road NE** **P.O. Box 97006** **Redmond, WA 98073-9706** **USA**

declares that the CE-marked product

Product Name:	LIFEPAK® 500 automated external defibrillator
Model Number:	3005400 (monophasic) 3011790 (biphasic)

complies with 93/42/EEC (Medical Device Directive) Class IIb, conformity assessed per Annex II.

Safety:	EN60601-1:1996/ IEC 60601-1:1995 internally powered, Type BF, Continuous operation. IEC 60601-2-4:1983
EMC:	EN60601-1-2:1993/IEC 60601-1-2: EN 55011:1991- Class B, Group 1 EN61000-4-2 1st edition - 8kV CD, 15 kV AD IEC61000-4-3 1st edition - 3 V/m EN61000-4-4 1st edition - Not Applicable IEC61000-4-5/EN61000-4-5 1st edition - Not Applicable

Supplementary Information:

Included are the following accessories and interconnecting cables:

QUIK-COMBO™ electrode set, PN 806086, 3008997, 3008826 or 3010188-001
FAST-PATCH® electrodes, PN 3006292 or 3010188-002
FAST-PATCH® defibrillation cable, PN 3010493
Sealed lead-acid battery, PN 3005379
Lithium battery, PN 3005380
Battery Charger (non-medical), PN 3006535
Data transfer cable (non-medical), PN 3005381

This product also complies with:

UL 2601-1:1994,
CSA C22.2 No. 601.1 and CSA C22.2 No. 601.2.4,
AAMI ES1, AAMI DF39

Redmond, May 1, 1999

Michael D. Willingham
Vice President of Quality and Regulatory Affairs

DECLARATION OF CONFORMITY

Ault, Incorporated
7300 Boone Avenue North
Minneapolis, MN 55428-1028
U.S.A.

We hereby declare under our sole responsibility that the product model(s) BCWA-042000-100A and BCWA-042000-100N (PHYSIO-CONTROL LIFEPAK 500 Battery Charger), a power supply intended for use as a battery charger in household and other similar applications, to which this declaration relates, meets the requirements of the following New Approach Directives:

- **Electro-Magnetic Compatibility (EMC) Directive** 89/336/EEC as demonstrated by compliance to EN50082-1:1992 Generic Immunity, IEC 801-2:1991 and IEC 1000-4-2:1995 Electrostatic Discharge Immunity, ENV50140:1993 and IEC 1000-4-3:1995 Radiated Electromagnetic Field Immunity, IEC 801-4:1988 Electrical Fast Transient/Burst, and EN 55022:1994 Class B limits for Radiated and Conducted Emissions.
- **Low Voltage Directive (LVD)** 73/23/EEC as demonstrated by compliance with EN 60065/09.93 Safety requirements for mains operated electronic and related apparatus for household and similar general use.

This declaration is backed by third party assessments to the noted European Norm standards. Ault Incorporated is an ISO 9001 registered firm, Certificate Number FM11881.

Tim Cassidy
Product Safety Engineer
28 October 1996

SAFETY INFORMATION

This section provides important information to help you operate the LIFEPAK 500 automated external defibrillator (AED). Familiarize yourself with all of these terms, warnings, and symbols.

Terms	page 1-2
General Warnings and Cautions	1-2
Symbols	1-3

TERMS

The following terms are used either in this manual or on the LIFEPAK 500 AED:

Danger: Immediate hazards that will result in serious personal injury or death.

Warning: Hazards or unsafe practices that could result in serious personal injury or death.

Caution: Hazards or unsafe practices that could result in minor personal injury, product damage, or property damage.

GENERAL WARNINGS AND CAUTIONS

The following section provides general warning and caution statements. Other specific warnings and cautions are provided as needed in other sections of this manual.

WARNINGS!

Shock hazard.

The defibrillator delivers up to 360 joules of electrical energy. Unless properly used as described in these Operating Instructions, this electrical energy may cause serious injury or death. Do not attempt to operate this device unless thoroughly familiar with these Operating Instructions, and the function of all controls, indicators, connections, and accessories.

Shock hazard.

Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.

Shock or fire hazard.

Do not immerse any portion of this device in water or other fluids. Avoid spilling any fluids on device or accessories. Do not clean with ketones or other flammable agents. Do not autoclave or sterilize this device or accessories unless otherwise specified.

Possible fire or explosion.

Do not use this device in the presence of flammable gases or anesthetics. Use care when operating this device close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move source away from patient during defibrillation.

Possible electrical interference with device performance.

Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI) which could affect the performance of this device. RFI may result in distorted ECG and failure to detect a shockable rhythm. Avoid operating device near cauterizers, diathermy equipment, or cellular phones. Maintain equipment separation of at least four feet and do not rapidly key EMS radios on and off. Contact Technical Support if assistance is required.

Possible electrical interference.

This defibrillator may cause electromagnetic interference (EMI) especially during charge and energy transfers. EMI may affect the performance of equipment operating in close proximity. Verify the effects of defibrillator discharge on other equipment prior to using defibrillator in an emergency situation, if possible.

Possible device shutdown.

Always have immediate access to a spare, fully-charged, properly maintained battery. Replace the battery when the device displays a low battery warning.

WARNINGS!

Possible improper device performance.

Using other manufacturers' cables, electrodes, or batteries may cause the device to perform improperly and invalidates the safety agency certification. Use only the accessories specified in these Operating Instructions.

Safety risk and possible equipment damage.

Monitors, defibrillators, and their accessories (including electrodes and cables) contain ferromagnetic materials. As with all ferromagnetic equipment, these products must not be used in the presence of the high magnetic field created by a Magnetic Resonance Imaging (MRI) device. The high magnetic field created by an MRI device will attract the equipment with a force sufficient to cause death or serious personal injury to persons between the equipment and the MRI device. This magnetic attraction may also damage the equipment. Skin burns will also occur due to heating of electrically conductive materials, such as patient leads and pulse oximeter sensors. Consult the MRI manufacturer for more information.

Shock hazard.

Do not insert a hand, foot, or any object other than a battery into the battery well of this device.

CAUTION!

Possible equipment damage.

This device may be damaged by mechanical or physical abuse such as immersion in water or dropping the device. If the device has been abused, remove it from use and contact a qualified service technician.

Note: Medtronic Physio-Control devices, electrodes and cables are latex-free.

SYMBOLS

The symbols below may be found in this manual or on various configurations of the LIFEPAK 500 AED and accessories:

Defibrillation protected, type BF patient connection

Attention, consult accompanying documents

Warning, high voltage

Indicator, steady display indicates battery is low, replace battery; flashing (key panel only) indicates replace battery immediately

Indicator, steady display indicates device requires service; flashing (key panel only) indicates service is required immediately

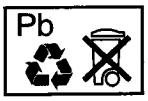
OK

Indicator, appears on Readiness Display indicating self-test completed successfully

▲ ▶

Buttons for setting the clock, transferring data, and setting options

Type BF patient connection



Rechargeable battery: recycle battery

Battery Charger: green LED indicates power is on

Battery Charger: battery is charging; amber LED indicates fast charge, green LED indicates trickle charge

Indoor use only

Safety Class II equipment (reinforced insulation)

Data Cable: to printer

Data Cable: to PC

Data Cable: to modem

Setup transfer cable

Lot code

Expiration date

REF

Reorder number

Do not reuse - single use only

CE 0123

Marking of conformity according to the Medical Device Directive 93/42/EEC by notified body TÜV Product Service GmbH

NRTL/C

Canadian Standards Association certification for the United States (Nationally Recognized Test Laboratory) and Canada

Cable Connector

Biphasic defibrillation shock

Medtronic Physio-Control 3D Biphasic technology trademark

GETTING READY

This section provides a basic orientation to the LIFEPAK 500 automated external defibrillator (AED) and describes how to prepare the AED for use.

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Controls, Indicators, and Connectors	2-2
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Factory Default Settings	2-11
Transferring Setup to Another LIFEPAK 500 AED	2-11
Connecting Electrodes to the AED	2-12

UNPACKING AND INITIAL INSPECTION

Remove the LIFEPAK 500 AED from the shipping container. Examine the AED and accessories for any sign of damage during shipping. Make sure that all the required supplies and accessories, including electrodes and batteries, are present. Save the shipping container and foam inserts for use in reshipping the AED.

CONTROLS, INDICATORS, AND CONNECTORS

Figure 2-1 and Table 2-1 provide an overview of the LIFEPAK 500 AED controls, indicators, and connectors. Figure 2-2 and Table 2-2 provide an overview of the accessories.

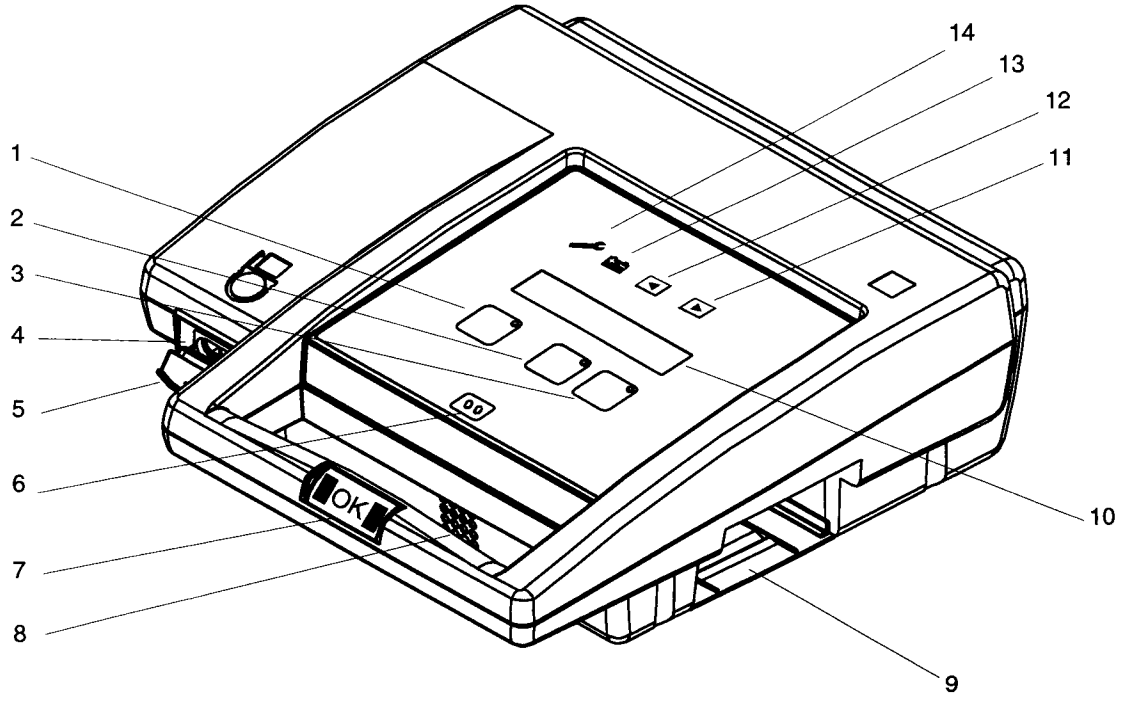


Figure 2-1 LIFEPAK 500 AED controls, indicators, and connectors

Table 2-1 Controls, Indicators, and Connectors

1		Green ON/OFF button turns the power on or off. The LED is lit whenever the AED is on.
2		Yellow ANALYZE button initiates analysis of the patient's ECG rhythm when pressed. The LED is lit while the AED analyzes the rhythm. The LED flashes to prompt the operator to press ANALYZE. **Note:** Does not apply to LIFEPAK 500 AEDs that do not have an ANALYZE button. In this case, the ANALYZE button is replaced by a blank "menu" button, and analysis occurs automatically.

3		Orange SHOCK button delivers energy. The LED flashes to prompt the operator to press SHOCK when the AED is fully charged.
4	Cable Connector	Allows connection to the following: • QUIK-COMBO electrodes (REDI-PAK or LLW) • Cables for connection to a printer, computer, modem, another LIFEPAK 500 AED, or FAST-PATCH electrodes • Test load for testing • Patient Simulator
5	Connector Cover	Protects Cable Connector.
6	Microphone	Allows input for audio recording.
7	Readiness Display	Displays OK when the automatic self-test completed successfully. If the self-test detects that service is required or if the device detects that the battery needs immediate replacement, the OK indicator disappears and a service and/or battery indicator appear(s). (Available on biphasic AED only.)
8	Speaker	Provides audio voice prompts and tones.
9	Battery Compartment	Accommodates a single removable battery pak that provides power for the AED.
10	Liquid Crystal Display (LCD)	Provides operating messages on two 20-character lines.*
11	▶ Right arrow button	Used to set the clock, transfer data, and set options.
12	▲ Up arrow button	Used to set the clock, transfer data, and set options.
13	 Low battery indicator	Steady display indicates the AED battery is low; flashing indicates replace battery immediately.
14	 Service indicator	Steady display indicates the AED requires service by authorized service personnel; flashing indicates service is required immediately.

* Accent marks are not included in operating message for international languages.

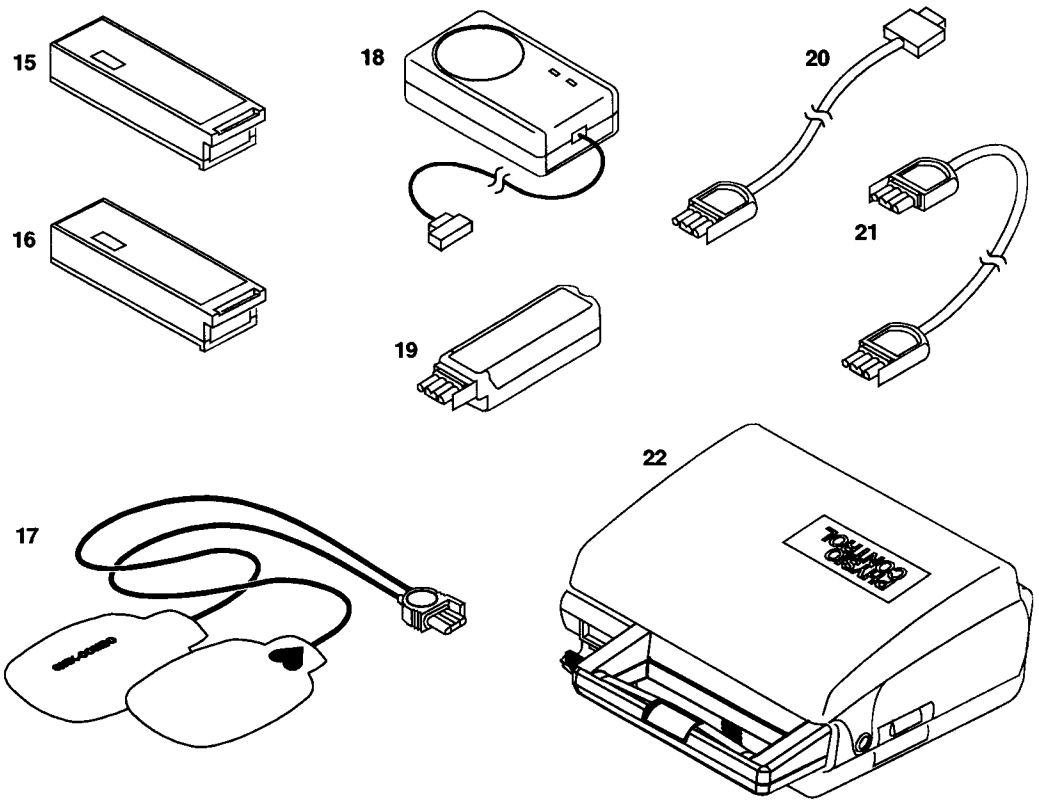


Figure 2-2 Accessories for the LIFEPAK 500 AED

Table 2-2 Accessories for the LIFEPAK 500 AED

15	LIFEPAK 500 nonrechargeable lithium battery pak	Provides power for the LIFEPAK 500 AED.
16	LIFEPAK 500 rechargeable SLA battery pak	Provides power for the LIFEPAK 500 AED. The SLA (Sealed Lead-Acid) battery pak is recharged by the battery charger listed below.
17	QUIK-COMBO electrodes	Allow delivery of therapy to the patient. Connect to the cable connector on the AED or to the QUIK-COMBO defibrillation cable (see Appendix D).
18	Battery Charger	Provides power to recharge the rechargeable SLA battery pak.
19	Test Load	Provides an external test load for the AED. Connects to the cable connector on the AED.
20	Data cable	One of three available cables shown. Allows transfer of data from AED to PC, modem, or printer. Plugs into the cable connector on the AED. Cables are 3-wire cables.
21	Setup Transfer Cable	Allows transfer of customized device setup from one LIFEPAK 500 AED to another.
22	Carrying case	Helps protect the AED and provides storage for electrodes.

ABOUT BATTERIES

Use either of the following battery types to power the LIFEPAK 500 AED:

- LIFEPAK 500 rechargeable SLA battery pak
- LIFEPAK 500 nonrechargeable lithium battery pak

To save battery life if the LIFEPAK 500 AED is accidentally turned on or left on, the AED has a battery conservation feature. If the AED is not connected to a patient and no buttons are pressed for 15 minutes, the AED will automatically turn off.

With a battery installed, the LIFEPAK 500 AED automatically performs daily auto tests when the AED is not in use. These auto tests, along with normal battery self-discharge, consume battery energy.

For information about maintaining or recharging the batteries, refer to page 5-8.

Battery Installation

To install a battery:

1 Insert the connector end of the battery into the battery compartment as shown in Figure 2-3.

2 Slide the battery all the way in until it latches securely.

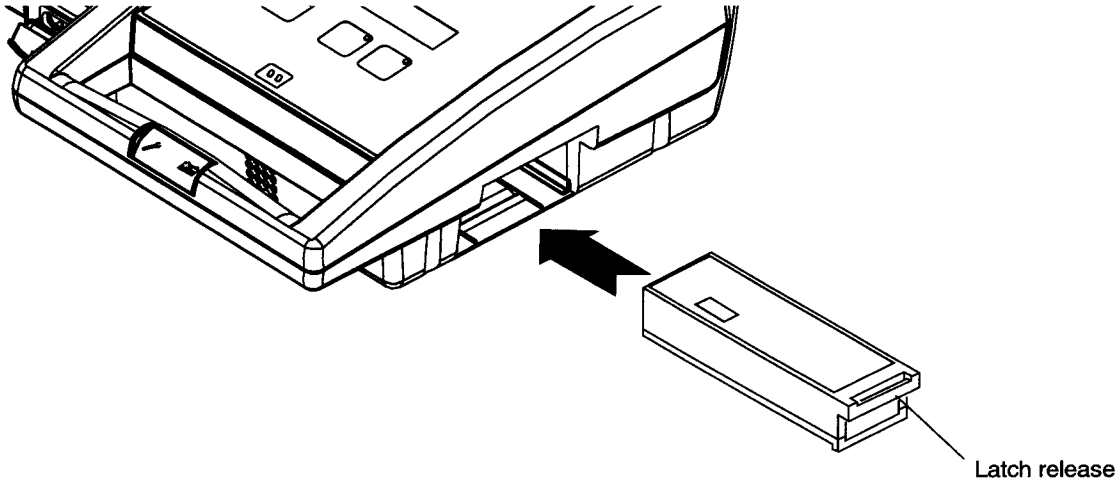


Figure 2-3 Battery installation

Battery Removal

To remove the battery:

1 Turn off the AED.

2 Lift the latch release on the battery and slide it out.

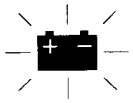
Note: When a battery is removed from the AED, battery and service indicators appear on the Readiness Display. After replacing the battery, turn on the device to reset the Readiness Display.

Low Battery Detection

Whenever the LIFEPAK 500 AED is turned on after it has been off for at least 60 seconds, it takes about 10 seconds to complete a self-test and to indicate a low or replace battery condition.

The AED monitors the battery power level and indicates when the battery should be replaced:

Indicator illuminates on the device key panel and appears on the Readiness Display and the LOW BATTERY message displays on the the LCD; battery is low.



Indicator flashes on and off on the device key panel, the REPLACE BATTERY message displays, and a voice prompt sounds; battery is low and should be replaced immediately.

Note: The Readiness Display battery indicator does not flash.

When the battery power is too low, the AED will automatically turn off. The service and battery indicators appear on the Readiness Display.

If the AED detects a low or replace battery condition during an auto test while it is not in use, audible beeps and the *REPLACE BATTERY* voice prompt will repeat every 20 minutes until the battery is replaced or battery power becomes too low to power the AED.

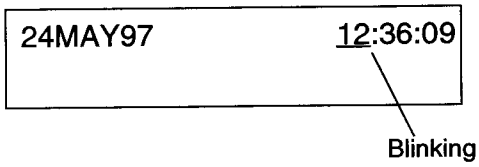
SETTING THE CLOCK

You may set the clock at any time except during the interval between patient care and data transfer to a computer or printer. Setting the clock during this interval will interfere with proper time synchronization.

To change the date and time:

1 Turn on the AED. (Be sure the AED has been off for at least 60 seconds and that nothing is connected to the AED.)

2 While the power is on, press the ▲ or ▶ button. The AED displays the date and time setting:



A value blinking on and off indicates that the value can be changed. The day, month, year, hour, and minutes values can be increased. The seconds value can be reset to zero.

3 To set the hour:
- Press the ▲ button to increase the value.
- Press the ▶ button to advance to the next field.

4 To set the minutes:
- Press the ▲ button to increase the value.
- Press the ▶ button to advance to the next field.

5 To reset the seconds value to zero:
- Press the ▲ button once.

Note: If the seconds value is less than 30 when reset, the minutes value stays the same. If the seconds value is greater than 30 seconds when reset, the minutes value increases by one.

- Press the ▶ button to advance to the next field.

6 Repeat Step 3 as needed to set the day, month, and year.

7 After the date and time are set, press ON/OFF to turn off the AED.

DEFINING SETUP OPTIONS

The following paragraphs describe the setup options that define some of the operating features for the LIFEPAK 500 AED. The user should become thoroughly familiar with the operating features particular to their LIFEPAK 500 AED.

Device ID

The DEVICE ID option assigns a unique identifier that is printed at the top of each report. Up to 20 characters with any combination of displayable characters can be used. The factory default setting is the AED serial number.

Modem Phone Number

The MODEM PHONE NUMBER option is the character string that the AED dials when it transfers data by modem. The dial string may include up to 20 characters as described in Table 2-3. The factory default dial string is blank.

Table 2-3 MODEM PHONE NUMBER **Dial String Characters**

Character	Description
P	Selects pulse dialing (only allowed as first character)
T	Selects tone dialing (only allowed as first character)
,	Inserts 2-second pause in dialing string
$	Waits for "bong" (calling card) tone
W	Waits for second dial tone
Alphanumeric characters	A, B, C, D and 0 through 9 (no special function)
* # ( )	Other characters (no special function)
+	Terminates dial string

Modem Selection

The MODEM SELECTION option determines the initialization string for one of the four modems listed in Table 2-4. Select the number that matches your modem. If you select 0, you must define the modem initialization string in the next option (MODEM INIT STRING). The factory default is 0.

Table 2-4 MODEM SELECTION **Numbers**

Number	Modem Type
0	No modem selected*
1	Hayes™ ACCURA 288 External Fax Modem Hayes ACCURA 336 External Fax Modem
2	USRobotics® Sportster® 28.8 Modem USRobotics Sportster 33.6 Modem
3	Motorola Lifestyle 28.8 Data/Fax Modem
4	SupraExpress™ 33.6 Fax Modem Hayes ACCURA 144 External Fax Modem Hayes ACCURA 56K External Fax Modem Hayes ACCURA 336 External Fax Modem with Voice Hayes ACCURA 336 External Fax Modem with Simultaneous Voice and Data Hayes ACCURA 56K Speakerphone Modem

* You must specify the modem initialization string in the MODEM INIT STRING option.

Note: The selection of commercially available modems changes rapidly. For more information or assistance regarding compatible modems, contact Medtronic Physio-Control Technical Support. In the USA call 1-800-442-1142. Outside the USA, contact your local Medtronic Physio-Control representative.

Modem Initialization String

The MODEM INIT STRING option defines the modem initialization string for a Hayes compatible modem (TIA/EIA-602). Up to 75 characters with any combination of displayable characters can be used. The factory default string is blank.

Note: The AED does not display MODEM INIT STRING unless the MODEM SELECTION is 0.

Energy Sequence

The ENERGY SEQUENCE option defines the three possible energy levels used by the LIFEPAK 500 AED.

For the LIFEPAK 500 AED with the monophasic defibrillation waveform, energy level 1 is fixed at 200 joules, energy level 2 has a choice of 200 joules or 300 joules, and energy level 3 is fixed at 360 joules. The factory default setting for the second energy level is 300 joules.

For the LIFEPAK 500 AED with the biphasic defibrillation waveform, energy level 1 is fixed at 200 joules; however, choices are available for energy levels 2 and 3. The choices include:

- Energy level 1 (200 joules)
- Energy level 2 (200, 225, 250, 275, 300 joules)
- Energy level 3 (200, 225, 250, 275, 300, 325, 360 joules)

The factory default setting is energy level 1 (200 joules), energy level 2 (300 joules), and energy level 3 (360 joules).

Energy Protocol

The ENERGY PROTOCOL option determines either a fixed or flexible sequence for your energy protocol. The factory default is flexible sequence.

Flexible sequence means the energy delivered for a shock increments only if an analysis immediately following a shock results in a SHOCK ADVISED decision. For example, if the AED energy sequence is set up as 200, 300, 360, flexible sequence means that the energy delivered for the first shock is 200 joules. If the arrhythmia is terminated by shock 1 and the next analysis results in a NO SHOCK ADVISED decision, the energy will **not** increase for the next shock. However, if the arrhythmia is not terminated by shock 1 and the next analysis results in a SHOCK ADVISED decision, the energy will increase to 300 joules.

Fixed sequence means that the energy delivered after the first shock of 200 joules increments from 200 to 300, and then to 360 joules, regardless of the post-shock ECG rhythm and subsequent analysis decision.

Display Energy

The DISPLAY ENERGY option determines whether or not the energy of the last shock is displayed during use. The factory default setting is ON.

Auto Analyze

The AUTO ANALYZE options are OFF, 1, or 2.

AUTO ANALYZE OFF: The operator must press ANALYZE to start every analysis.

AUTO ANALYZE 1: The second and third rhythm analyses of each three-shock set start automatically without requiring the operator to press ANALYZE. (The operator must always press ANALYZE to start the first analysis of a three-shock set and to analyze after a NO SHOCK ADVISED message or CPR cycle.) The factory default setting is AUTO ANALYZE 1.

AUTO ANALYZE 2: **ALL** analysis cycles are initiated automatically. LIFEPAK 500 AEDs that do not have an ANALYZE button operate in this mode.

CPR Time

The CPR TIME 1 AND 2 options define a time period during which you are prompted to perform CPR. The choices are: 0, 15, 30, 45, 60, 90, 120, and 180 seconds and 999 (infinite CPR Time). For all selections except 0 and 999, the AED prompts you to perform CPR and then displays a countdown timer. If CPR Time 999 is selected, the AED prompts you to perform CPR, but does not display the countdown timer. The AED will not prompt you to PUSH ANALYZE, although you may do so at any time to initiate an analysis.

CPR Time 1 defines the CPR period following each 3-shock set. CPR Time 2 defines the CPR period following a NO SHOCK ADVISED message. Check your local protocol for the appropriate CPR Time.

The CPR TIME 1 AND 2 factory default settings are 60 seconds each.

Note: When a NO SHOCK ADVISED message occurs immediately after a shock, the CPR period is the same as CPR Time 1.

Note: CPR Time 0 is not available if AUTO ANALYZE 2 is selected on AEDs that have an ANALYZE button or on AEDs that do not have an ANALYZE button. CPR Time 999 is not available on AEDs that do not have an ANALYZE button.

CPSS during CPR

The CPSS DURING CPR option determines whether or not Continuous Patient Surveillance System (CPSS) is active during CPR Time. The factory default setting is OFF. This setup option is only available with AEDs that have an ANALYZE button and are configured with AUTO ANALYZE OFF or AUTO ANALYZE 1.

If the CPSS DURING CPR option is ON, the AED "watches" for potentially shockable ECG rhythms (e.g., refibrillation) throughout CPR Time. When CPSS detects a potentially shockable ECG rhythm, the AED prompts PUSH ANALYZE, and CPR is temporarily interrupted while the user stays clear of the patient during the analysis. With CPSS on during CPR Time, CPR artifact may or may not be interpreted as a shockable ECG rhythm. However, when CPSS is off during CPR, the presence of a shockable ECG rhythm will not be detected until CPR Time is over or the next analysis.

The determination of whether or not the CPSS DURING CPR option is selected to be turned ON may be based on the following:

- Post shock CPR protocol
- Effects of interrupting CPR
- Skill and training level of the care providers

If CPSS is turned on during CPR Time, protocols should be developed to manage the possible repeated false positives of CPSS alerts during CPR. The ability of the personnel in the service to follow such a protocol should be taken into account. For more information, refer to Appendix A.

Motion Detection

The MOTION DETECTION option determines whether or not the motion detection system is active during analysis. The factory default setting is ON.

When this option is off, analysis of the ECG is allowed to proceed uninhibited by the presence of motion, which may or may not cause artifact on the ECG. Artifact on the ECG may lead to erroneous ECG interpretations. However, when this option is on, motion that is detected may temporarily inhibit analysis from proceeding, for example in patients with agonal breathing.

The determination of whether or not the MOTION DETECTION OPTION is selected to be turned off includes the consideration of:

- Skill and training level of the care providers
- Frequency of the occurrence of agonal breathing
- Other motion artifact during use of the AED

For more information, refer to Appendix A.

Asystole Detector

This option enables the ASYSTOLE DETECTOR. When active, the ASYSTOLE DETECTOR notifies the user that asystole has been detected for a number of consecutive analyses over a period of time. The time interval determines how long asystole must be detected before the ASYSTOLE message appears. The time intervals that can be selected are: 4 to 60 minutes (in one-minute intervals). The factory default setting is OFF.

Audio Recording

AUDIO RECORDING is only displayed if the option is installed. The AUDIO RECORDING option may be ON or OFF. If it is ON, the AED records the audio during patient care. If it is OFF, the AED does not record the audio. The factory default setting is ON.

Paper Size

The PAPER SIZE option defines the size of the paper for the printer used to print out AED data. The choices are 8 1/2 x 11 inches and A4. The factory default is 8 1/2 x 11 inches.

Incident ID

An INCIDENT ID number can be entered prior to transferring patient data to a computer through a modem. You can use up to 20 characters with any combination of displayable characters. The factory default setting is OFF.

Transfer Setup

Once the setup in one LIFEPAK 500 AED has been customized, the TRANSFER SETUP option supports the transfer of this setup to other LIFEPAK 500 AEDs. Setup transfers are possible only between LIFEPAK 500 AEDs with the same button configuration (for example, 2 button to 2 button) and defibrillation waveform.

FACTORY DEFAULT SETTINGS

Factory default settings for setup options are summarized in Table 2-5.

Table 2-5 Setup Options and Factory Default Settings

Setup Options	Factory Default Settings
Device ID	AED serial number
Modem phone number	Blank
Modem selection	0
Modem initialization string	Blank
Energy sequence	200–300–360 joules
Energy protocol	Flexible sequence
Display energy	ON
Auto analyze	1
CPR time 1	60 seconds
CPR time 2	60 seconds
CPSS during CPR	OFF
Motion detection	ON
Asystole detector	OFF
Audio recording	ON
Paper size	8 1/2 x 11 inches
Incident ID	OFF
Transfer setup	User feature (always active)

For more information on changing setup options, refer to the LIFEPAK 500 automated external defibrillator Setup Instructions (PN 3012275).

TRANSFERRING SETUP TO ANOTHER LIFEPAK 500 AED

You can transfer the clock setting and all setup information except DEVICE ID from one LIFEPAK 500 AED to an identical AED using the Transfer Setup option. Identical AEDs are devices that have the same button configuration and defibrillation waveform.

Note: Only LIFEPAK 500 AEDs with software version 4.2 or later can transfer and receive setup data. Attempting to transfer setup data to devices with software version 4.0 may induce erroneous faults in the receiving device.

To transfer the setup:

1 From within the SETUP MODE, push ANALYZE (or blank "menu" button) to advance to the transfer setup option. The AED displays the TRANSFER SETUP screen:

TRANSFER SETUP TO SEND PUSH ▶

2 Connect the equipment as shown in Figure 2-4:
   - Connect the Setup Transfer Cable to the AED that has the setup you wish to transfer (original AED).
   - Connect the other end of the Setup Transfer Cable to the AED that you wish to receive the new setup (receiving AED).

   Note: Both AEDs must have the same button configuration and defibrillation waveform.

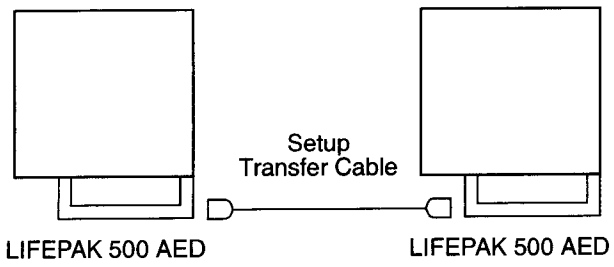


Figure 2-4 Setup transfer connections

3 Turn on the receiving AED and wait for CONNECT ELECTRODES message to appear.

4 Push the ▶ button on the original AED to send the setup to the receiving AED.

   During setup transfer, the original AED displays the SENDING message. The receiving AED displays a blank screen.

   After the original AED successfully transfers the setup, it displays the SEND COMPLETE message. The receiving AED turns itself off, turns itself back on, and then displays the CONNECT ELECTRODES message.

5 To transfer the setup from the original AED to additional AEDs:
   - Turn off the receiving AED.
   - Disconnect the Setup Transfer Cable from the receiving AED.
   - Repeat Steps 2 through 4.

6 When finished, disconnect the Setup Transfer Cable, turn off both AEDs, and prepare them for patient use.

   Note: The original AED does not transfer the device ID to the receiving AED. To change the device ID on a receiving AED, refer to the LIFEPAK 500 automated external defibrillator Setup Instructions (PN 3012275).

CONNECTING ELECTRODES TO THE AED

You can connect the QUIK-COMBO electrodes with the REDI-PAK preconnect system to the AED before patient care to save time. To connect the REDI-PAK-type QUIK-COMBO electrodes:

1 Inspect the electrode package and confirm that the expiration date has not passed.

2 Remove the clear plastic pouch to expose the QUIK-COMBO electrode connector.

3 Open the connector cover on the AED as shown in Figure 2-5.

4 Insert the electrode connector firmly into the cable connector on the AED as shown in Figure 2-5.

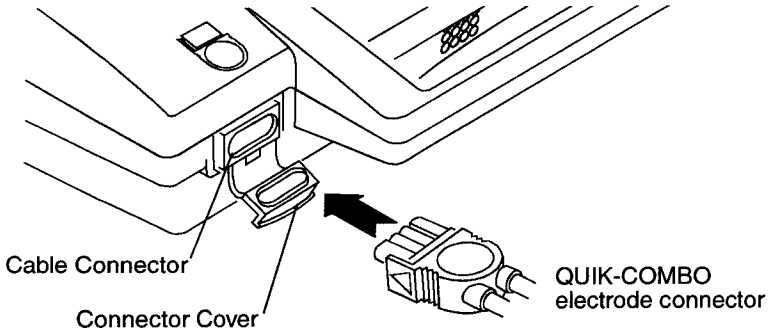


Figure 2-5 Connecting the QUIK-COMBO electrodes

5 Store the electrodes in the carrying case or the electrode storage tray.

6 Do not open the electrode package until immediately prior to patient use.

If you use QUIK-COMBO electrodes without the preconnect system, you should:

- Not open the electrode package until immediately prior to patient use.
- Inspect the electrode package and confirm that the expiration date has not passed.
- Store the electrode package in the carrying case or electrode storage tray.
- When ready for patient use, open the electrode package and connect the electrodes to the AED as shown in Figure 2-5 above.

Note: If you are using FAST-PATCH electrodes, refer to Appendix C.

USING THE LIFEPAK 500 AED

This section describes how to use the LIFEPAK 500 automated external defibrillator (AED) for ECG analysis and defibrillation. The actual clinical procedures that you use may vary according to your local protocol.

Warnings and Cautions	page 3-2
Preparing the AED for Operation	3-3
AED Operation	3-3
AED Prompts	3-4
Patient Care Transfer to a Different Device	3-9
Troubleshooting During Patient Care	3-9

WARNINGS AND CAUTIONS

WARNINGS!

Shock hazard.

This defibrillator delivers up to 360 joules of electrical energy. When discharging the defibrillator, do not touch the disposable therapy electrodes.

Shock hazard.

If a person is touching the patient, bed, or any conductive material in contact with the patient during defibrillation, the delivered energy may be partially discharged through that person. Clear everyone from contact with the patient, bed, and other conductive material before discharging the defibrillator.

Shock hazard.

To remove an unwanted charge, disconnect the electrode cable from the device, wait for the device to automatically remove the charge, or turn off the AED.

Possible fire, burns, and ineffective energy delivery.

Do not discharge standard paddles on top of therapy electrodes or ECG electrodes. Do not allow therapy electrodes to touch each other, ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating energy away from the heart muscle.

Possible skin burns.

During defibrillation, air pockets between the skin and therapy electrodes can cause patient skin burns. Apply therapy electrodes so that entire electrode adheres to skin. Do not reposition the electrodes once applied. If the position must be changed, remove and replace with new electrodes.

Possible skin burns and ineffective energy delivery.

Therapy electrodes that are dried out or damaged may cause electrical arcing and patient skin burns during defibrillation. Do not use electrodes that have been removed from foil package for more than 24 hours. Do not use electrodes beyond expiration date. Check that electrode adhesive is intact and undamaged. Replace therapy electrodes after 50 shocks.

Pediatric patient safety risk.

This AED is not designed or tested to interpret pediatric ECG rhythms or administer energy at pediatric joule settings. The American Heart Association recommends AEDs be used only on patients who are more than eight years old.

CAUTION!

Possible equipment damage.

Before using this AED, disconnect all equipment from the patient that is not defibrillator-protected.

PREPARING THE AED FOR OPERATION

Follow these steps to make sure that the AED is always ready for use:

- Properly maintain the AED and batteries as described on page 5-8 of this manual.
- Make sure that the defibrillation electrodes are available and properly stored in the AED carrying case or electrode tray.
- Keep the following supplies readily accessible:
  - Spare, properly maintained battery
  - Spare defibrillation electrodes
  - Supplies to clean and shave the electrode sites on the patient
- Keep the AED and accessories within an optimal temperature range of 15–35°C (40–95°F).

QUIK-COMBO and FAST-PATCH electrodes are pre-gelled, self-adhesive electrodes that allow hands-free defibrillation. They are designed for use with devices equipped with the appropriate connector or therapy cable. For more information about these electrodes, refer to the respective electrode operating instructions.

AED OPERATION

To prepare for ECG analysis and defibrillation:

1 Verify that the patient is in cardiac arrest (unconscious, no respiration, no pulse).

2 Press ON/OFF to turn on the AED (the green LED will light). The *CONNECT ELECTRODES* message and voice prompt will occur until the patient is connected to the AED.

3 Prepare the patient for electrode placement:
- If possible, place the patient on a hard surface away from standing water or conductive material.
- Remove clothing from the patient's upper torso.
- Remove excessive hair from the electrode sites. If shaving is necessary, avoid cutting the skin.
- Clean the skin and dry it briskly with a towel or gauze.
- Do not apply alcohol, tincture of benzoin, or antiperspirant to the skin.

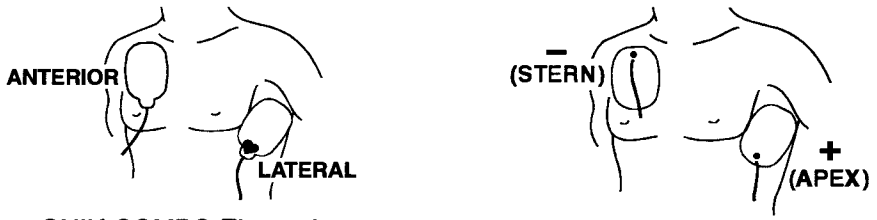
4 Apply the electrodes to the patient's chest:

WARNING!

Possible ECG misinterpretation.

Do not place therapy electrodes in the anterior-posterior position when operating this AED. A shock or no shock decision may be inappropriately advised. The shock advisory algorithm requires the electrodes to be placed in the anterior-lateral (Lead II) position.

- Place the ♥or + electrode lateral to the patient's left nipple with the center of the electrode in the midaxillary line, if possible. (See Figure 3-1.)
- Place the other electrode on the patient's upper right torso, lateral to the sternum and below the clavicle as shown in Figure 3-1.
- Starting from one end, press the electrodes firmly onto the patient's skin.



QUIK-COMBO Electrodes FAST-PATCH Electrodes

Figure 3-1 Anterior-lateral position

5 Connect the electrode connector to the AED (if it is not already connected).
6 Follow the screen messages and voice prompts provided by the AED.

Special Situations for Electrode Placement

When placing electrodes on the patient, be aware of the following special situations.

Obese Patients or Patients with Large Breasts

Apply the electrodes to a flat area on the chest, if possible. If skin folds or breast tissue prevent good adhesion, spread skin folds apart to create a flat surface.

Thin Patients

Follow the contour of the ribs and spaces when pressing the electrodes onto the torso. This limits air space or gaps under the electrodes and promotes good skin contact.

WARNING!

Possible interference with implanted electrical device.

Defibrillation may cause implanted electrical devices to malfunction. Place therapy electrodes away from implanted devices if possible. Check implanted device function after defibrillation.

Patients with Implanted Pacemakers

If possible, place defibrillation electrodes away from the internal pacemaker generator. Treat this patient like any other patient requiring emergency care. Pacemaker pulses may prevent advisement of an appropriate shock, regardless of the patient's underlying rhythm.

Patients with Implanted Defibrillators

Apply the electrodes in the anterior-lateral position. Treat this patient like any other patient requiring emergency care.

AED PROMPTS

The following paragraphs describe typical scenarios that might occur during AED operation. Topics include:

- First analysis cycle
- Shock advised
- Subsequent analysis cycles
- No shock advised
- CPR Time
- Shock counter
- Motion detection
- Continuous Patient Surveillance System - Check Patient Alert
- Electrodes off detection

For a more detailed description of how the AED analyzes the patient ECG, refer to page A-2.

Note: Accent marks are not included in message prompts for international languages.

WARNING!

Possible misinterpretation of data.

Do not analyze in a moving vehicle. Motion artifact may affect the ECG signal resulting in an inappropriate shock or no shock advised message. Motion detection may delay analysis. Stop vehicle and stand clear of patient during analysis.

Possible misinterpretation of data.

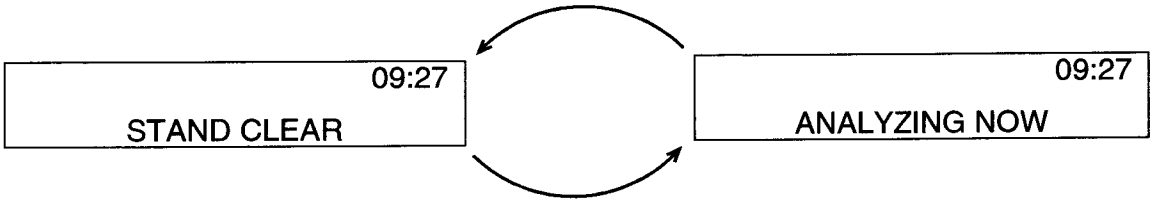
Do not move the AED during analysis. Moving the AED during analysis may affect the ECG signal resulting in an inappropriate shock or no shock advised decision. Do not touch the patient or the AED during analysis.

First Analysis Cycle

When you turn on the power and first apply electrodes to the patient, the AED will either analyze automatically or prompt you to press ANALYZE, depending on the auto analyze configuration.

If you hear the *PUSH ANALYZE* voice prompt and see the ANALYZE LED flash, press ANALYZE.

When the AED begins to analyze the patient's ECG, the AED beeps twice and alternately displays two messages:



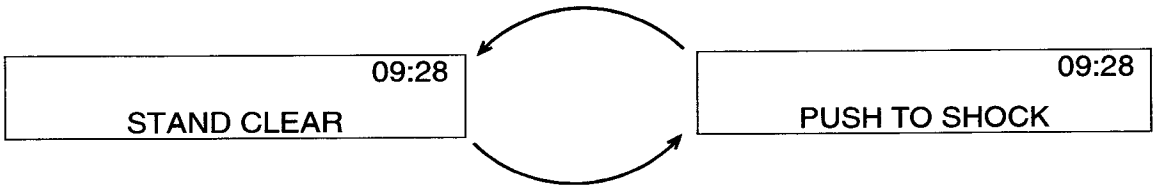
You will hear the *STAND CLEAR, ANALYZING NOW, STAND CLEAR* voice prompt. The ECG analysis requires about 9 to 13 seconds. The ANALYZE LED (if present) is on during analysis.

Shock Advised

If the AED detects a shockable ECG rhythm, it displays this message:

You will hear the *SHOCK ADVISED* voice prompt. The AED begins charging for Shock #1. A rising tone indicates that the AED is charging.

When charging is complete, the AED alternately displays two messages:



You will hear the *STAND CLEAR, PUSH TO SHOCK* voice prompt followed by the "shock ready" tone (a loud, high-pitched, two-tone sound). The SHOCK LED flashes.

- Press SHOCK to discharge the AED.
- If you do not press SHOCK within 15 seconds, the AED disarms the SHOCK button, and the CHARGE REMOVED message appears.

Subsequent Analysis Cycles

If the option AUTO ANALYZE 1 or 2 is selected, the AED automatically analyzes the patient's ECG rhythm after Shock #1 is delivered. If the AUTO ANALYZE option is off, the AED displays PUSH ANALYZE after Shock #1. (You will also hear the *PUSH ANALYZE* voice prompt and see the ANALYZE LED flash.) You must press ANALYZE to begin the analysis.

The second analysis and shock sequence is the same as that described for Shock #1. However, the energy levels for Shock #2 and Shock #3 depend on the value selected for the ENERGY SEQUENCE and the ENERGY PROTOCOL options. When a NO SHOCK ADVISED decision immediately follows a shock, the energy level will not increase for the next shock if FLEXIBLE SEQUENCE is enabled.

Note: If FIXED SEQUENCE is enabled, the energy level for shocks will increment regardless of the analysis decision.

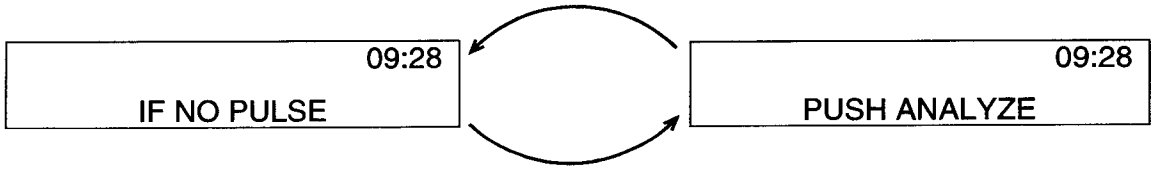
No Shock Advised

If the AED detects a nonshockable ECG rhythm, it displays this message:

You will hear the *NO SHOCK ADVISED* voice prompt. The AED will not charge, and no shock can be delivered.

After NO SHOCK ADVISED, the AED enters CPR TIME if CPR TIME is set to 15 seconds or more. If CPR TIME is set to 0, the AED displays this message:

You will hear the *CHECK FOR PULSE* voice prompt. After 10 seconds, the AED displays two alternating messages:



You will hear the *IF NO PULSE, PUSH ANALYZE* voice prompt.

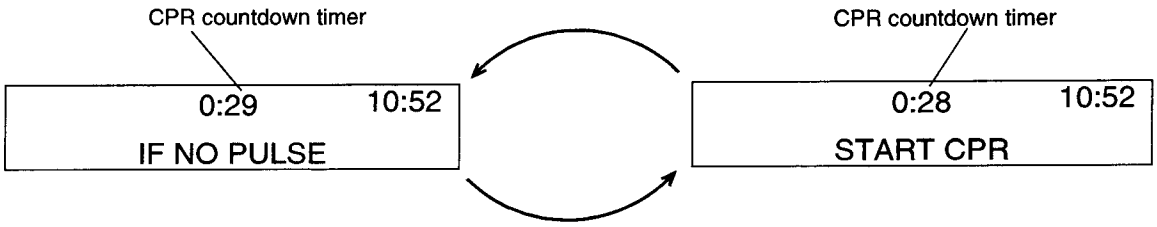
CPR Time

At the beginning of CPR TIME, the AED first displays this message:

You will hear the *CHECK FOR PULSE* voice prompt.

After 10 seconds, the AED alternately displays two messages, the message content depends on the value selected for the CPR TIME option.

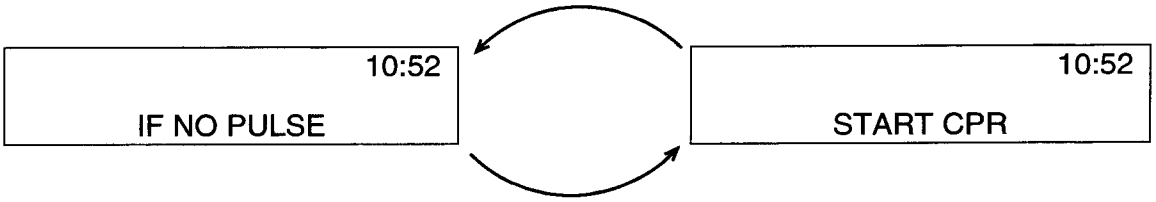
If CPR TIME is set to 15, 30, 45, 60, 90, 120, or 180 seconds, the AED displays these two messages:



The CPR countdown timer indicates CPR time remaining.

You will hear the *IF NO PULSE, START CPR* voice prompt. The messages alternate for the remaining CPR TIME. You can press ANALYZE (if button present) to stop CPR TIME and start an analysis cycle.

If CPR TIME is set to 999 (infinite CPR TIME), the AED displays these two messages:

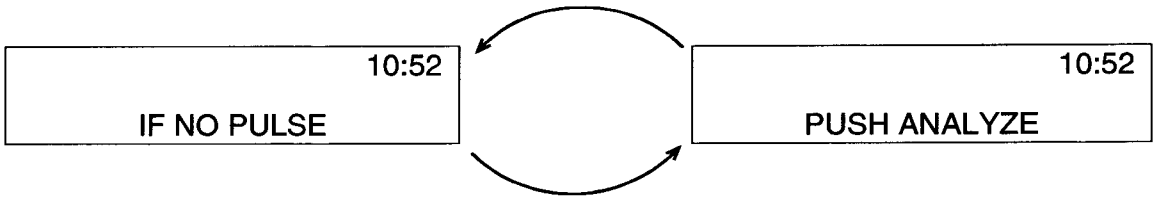


You will hear the *IF NO PULSE, START CPR* voice prompt. The messages alternate without further voice prompts. You can press ANALYZE (if button present) to stop CPR TIME and start an analysis cycle at any time.

After CPR Time

After CPR TIME, the AED displays this message:

You will hear the *CHECK FOR PULSE* voice prompt. After 10 seconds, the AED displays two alternating messages if AUTO ANALYZE is off or AUTO ANALYZE 1 is selected:

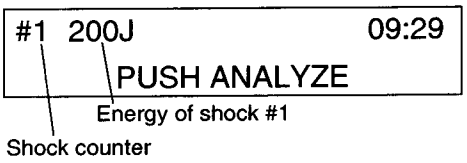


You will hear the *IF NO PULSE, PUSH ANALYZE* voice prompt.

Note: If AUTO ANALYZE 2 is selected or for LIFEPAK 500 AEDs that do not have an ANALYZE button, analysis will begin automatically at the end of CPR Time. You will hear *STAND CLEAR, ANALYZING NOW, STAND CLEAR*. Stop CPR immediately and stay clear of patient during the analysis.

Shock Counter

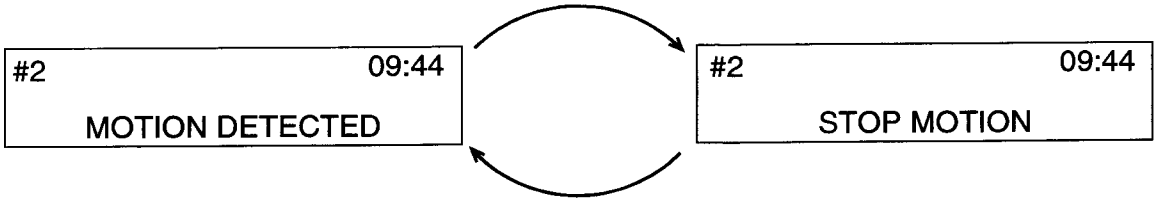
The AED displays the shock counter in the upper-left corner of the LCD:



The shock counter indicates how many shocks have been delivered to the patient. Following the shock counter, the energy for that shock number may be displayed (optional). The shock counter resets whenever the AED is turned off for at least 60 seconds.

Motion Detection

If the AED is configured with MOTION DETECTION ON and the AED detects motion during the ECG analysis, the AED alternately displays two messages:



You will hear the *MOTION DETECTED, STOP MOTION* voice prompt, followed by a warning tone. If the motion ceases within 20 seconds, analysis will continue. If the motion does not cease within 20 seconds, analysis will stop. You must then push ANALYZE (if button present) to restart analysis. If AUTO ANALYZE 2 is selected and in LIFEPAK 500 AEDs that do not have an ANALYZE button, analysis will restart automatically. Refer to troubleshooting on page 6-2 for possible causes and suggested actions.

If the AED is configured with MOTION DETECTION OFF, the ECG analysis proceeds uninhibited by the presence of motion. There is no motion detected verbal or text prompt if motion is present during ECG analysis.

Continuous Patient Surveillance System — Check Patient Alert

The Continuous Patient Surveillance System (CPSS) is active immediately after the AED is turned on when the patient is connected, and after CPR time. In addition, CPSS may be configured to be active during CPR time.

Note: CPSS is not active if AUTO ANALYZE 2 is selected or in LIFEPAK 500 AEDs without an ANALYZE button.

If the CPSS detects a potentially shockable rhythm, the AED displays this message:

You will hear the *PUSH ANALYZE* voice prompt accompanied by a warning tone. You should:

- Stop all patient and vehicle movement.
- Confirm that the patient is in cardiac arrest.
- Press ANALYZE. Stay clear of the patient and allow the AED to analyze the patient's rhythm.
- Follow the screen messages and voice prompts provided by the AED.

Electrodes Off Detection

If the AED detects that the electrodes are not properly connected to the AED or the patient, the AED displays this message:

You will hear the *CONNECT ELECTRODES* voice prompt followed by three warning beeps. Refer to troubleshooting on page 6-2 for possible causes and suggested actions.

Asystole Detector

If the AED has been configured for the asystole detector to be active, the AED displays this message after NO SHOCK ADVISED decisions occur with asystole present and when the asystole detector time interval has been reached.

You will hear the *ASYSTOLE* voice prompt, which will repeat periodically until the next analysis.

PATIENT CARE TRANSFER TO A DIFFERENT DEVICE

To transfer patient care between devices equipped with identical therapy cable connectors:

1 Turn off the device connected to the patient.
2 Leave the defibrillation electrodes on the patient; disconnect the electrodes from the therapy cable or the device.
3 Connect the therapy electrodes to the next device.

To transfer patient care between devices not equipped with identical therapy cable connectors:

1 Turn off the device connected to the patient.
2 Remove the defibrillation electrodes currently on the patient.
3 Apply defibrillation electrodes that are compatible with the receiving device.
4 Follow the instructions for the receiving device.

TROUBLESHOOTING DURING PATIENT CARE

For troubleshooting during patient care, refer to Table 6-1, page 6-2.

DATA MANAGEMENT

This section describes how to store and transfer LIFEPAK 500 automated external defibrillator (AED) data to a computer or a modem. Topics include:

Overview of Data Storage and Retrieval	page 4-2
Sending Data to a Computer by Modem	4-5
Sending Data to a Computer by Direct Connection	4-7
Sending Data to a Printer	4-8

OVERVIEW OF DATA STORAGE AND RETRIEVAL

Every time you use the LIFEPAK 500 AED on a patient, data is stored digitally inside the AED. This data allows post-incident review for quality control, training, and research purposes. Print or transfer this data as soon as possible to save the information.

The following paragraphs describe how the LIFEPAK 500 AED stores and retrieves data.

Overview of Data Storage

Whenever power is on, the LIFEPAK 500 AED automatically stores the data illustrated in Figure 4-1.

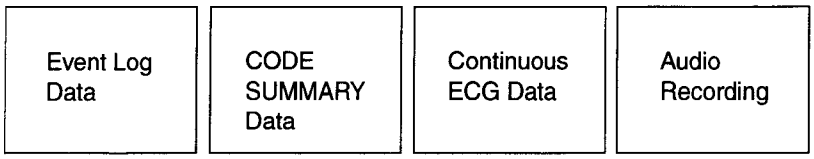


Figure 4-1 Data stored by the LIFEPAK 500 AED

- Event Log Data — A chronological log of all events. An event is a specific action by the operator or AED, such as:
  - Power on
  - Patient connected
  - Analysis started
  - Shock advised
  - Shock delivered

  Refer to page 6-7 for a list of all the event types.
- CODE SUMMARY Data — A summary of critical resuscitation events and the ECG rhythm segments associated with those events.
- Continuous ECG Data — Between 20 and 80 minutes of the patient ECG rhythm from the time of power-on to power-off. Varies with the configuration of the AED and whether Audio Recording is installed and enabled. (See Specifications, page 5-15.) Data collection stops when maximum recording times are exceeded.
- Audio Recording — Approximately 20 minutes of audio data recorded at the scene, such as operator remarks and AED voice prompts or tones. (The audio recording option must be installed and enabled.) Data collection stops when maximum recording times are exceeded.

Patient Records

A patient record is created when the AED is connected to a patient and begins to store data. The AED stores data from the time that you turn the AED on until you turn the AED off. The LIFEPAK 500 AED can store a maximum of two patient records:

- Current Patient — The most recent patient record stored
- Previous Patient — The patient record stored prior to the Current Patient

The data stored for the Current Patient and Previous Patient is illustrated in Figure 4-2.

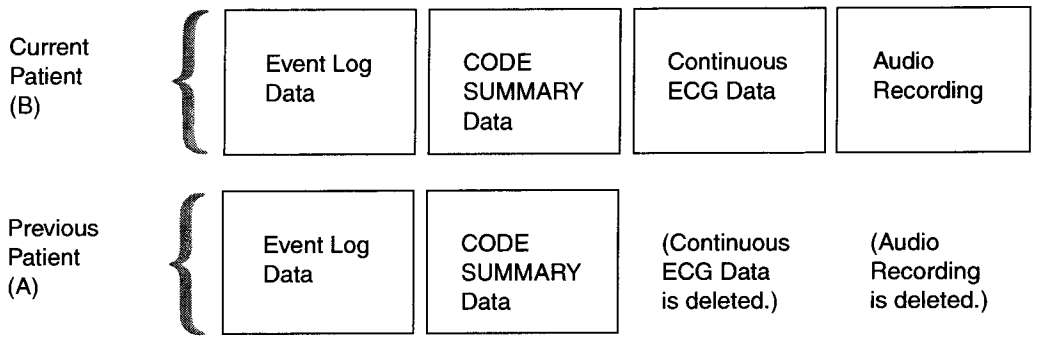


Figure 4-2 Comparison of data stored for the Current Patient and Previous Patient

The AED stores all data for the Current Patient (B). However, the AED only retains the Event Log and CODE SUMMARY data for the Previous Patient (A).

Information Stored When Creating a New Patient Record

When the AED creates a new patient record, the following occurs:

- The AED stores all data for the newest patient record, Patient C (refer to Figure 4-3). Patient C is now the Current Patient.
- The AED deletes the ECG and audio recording data for Patient B. The AED retains only the Event Log and CODE SUMMARY data. Patient B is now the Previous Patient.
- The AED deletes all data for the oldest patient record, Patient A.

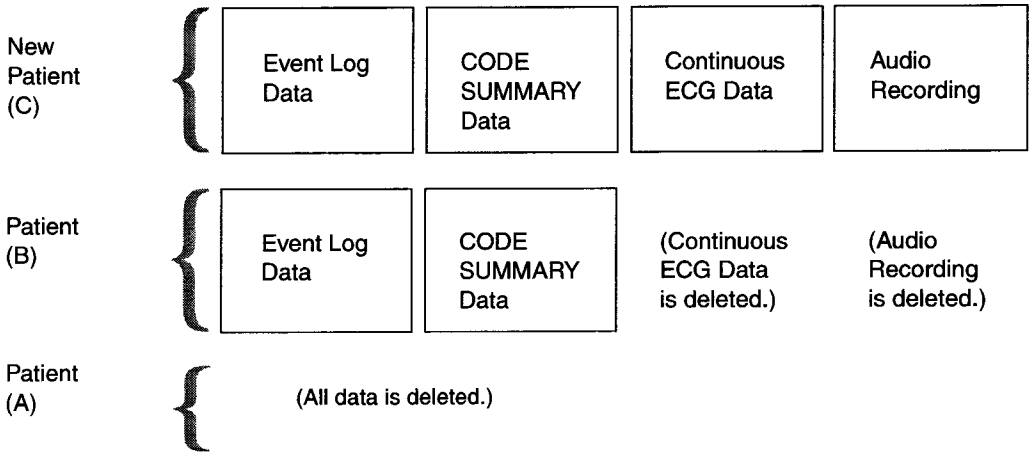


Figure 4-3 Data stored when the AED stores a new patient record

Conditions for Creating a New Patient Record

To begin a new patient record, the following conditions must occur:

- The AED must be turned off for at least 60 seconds, then turned on.
- Electrodes must be connected to the patient.

You can turn off the AED briefly without affecting the Current Patient. For example, you can change the battery. If you restore power in less than 60 seconds, the AED resumes storing data for the Current Patient.

If you do not connect electrodes to a patient or a simulator, you can turn on the AED and not affect the Current Patient. For example, you can turn on the AED to test it with the external test load or to transfer data. As long as you do not connect the electrodes to a new patient or an ECG simulator, the AED does not create a new patient record.

As soon as you turn on the AED, the AED begins storing data for a new patient record. However, if you do not connect electrodes to a patient within 3 minutes, the AED stops storing data.

- If you then connect electrodes, the AED resumes storing data and creates a new Current Patient.
- If, however, you turn off the AED without ever connecting the electrodes, the AED does *not* create a new Current Patient. The AED will delete the initial 3 minutes of data, and all previously stored data will remain unchanged. This prevents erasing data each time you turn on the AED to transfer data or perform maintenance.

Test Log

The LIFEPAK 500 AED also stores a Test Log, a list of the 30 most recent auto-tests and manual tests. The Test Log lists the test results and any fault codes detected. The Test Log is printed automatically when data is sent to a printer. As an option, the Test Log may be printed from a computer.

Overview of Data Retrieval

There are three ways you can retrieve data from the LIFEPAK 500 AED:

- Send the data to a computer by modem.
- Send the data to a computer by direct connection.
- Send the data to a printer.

The AED does not delete data after it is transferred. Data is only deleted when new patient records are created. Table 4-1 describes the stored data and how you can retrieve it.

Table 4-1 LIFEPAK 500 AED Data and Retrieval

TYPE OF DATA RETRIEVAL	MODEM	COMPUTER	PRINTER
Event Log Data	Yes	Yes	Yes
CODE SUMMARY data	Yes	Yes	Yes
Continuous ECG[1]	Yes	Yes	No
Audio Recording[1]	Yes[2]	Yes[2]	No
Test Log	Yes	Yes	Yes

[1] Available for the Current Patient only.

[2] To play the audio recordings, a sound card, sound card software, and the QUIK-VIEW 500 data review program or CODE-STAT Suite must be installed in the computer.

SENDING DATA TO A COMPUTER BY MODEM

These paragraphs describe the resources, equipment connections, and procedures required to send LIFEPAK 500 AED data to a computer by modem.

Required Resources

Table 4-2 summarizes the resources required to send data to a computer by modem.

Table 4-2 Required Resources for Sending Data to a Computer by Modem

DESCRIPTION	
Required Resources at Local Site	
Modem Cable (for use with LIFEPAK 500 AED)	
Modem that supports the TIA/EIA-602 command set	
Modem power cord or power adapter (if required)	
Telephone cord (with RJ11 connectors)	
Analog telephone line[1]	
Required Resources at Destination Site	
Modem that supports the Hayes AT command set	
Personal Computer:	- QUIK-VIEW 500 data review program or CODE-STAT Suite data management system - Microsoft Windows 3.1 or later for Data Transfer 500, and for QUIK-VIEW 500 if audio review is not needed. Microsoft Windows 95 for QUIK-VIEW 500 if audio review is needed - Microsoft Windows 95 or Windows NT 4.0 for CODE-STAT Suite
Cables as required	
Analog telephone line[1]	

[1] Most internal telephone lines for integrated office telephone systems are digital lines. Make sure that you connect the modem to an external analog telephone line like the type used for fax machines.

Setup Options

Make sure that the AED setup options are properly defined for the modem initialization string and destination phone number. Refer to page 2-7 for information about the modem setup options.

Note: Remember to include in the dial string any special characters that are required to dial the destination (such as "9" or a pause).

Procedure for Sending Data

Perform these steps to send the data:

1 Make sure that the equipment at the destination site is properly connected.

2 Make sure that the destination computer power is on and that the QUIK-VIEW 500 data review program or CODE-STAT Suite program is ready to receive data.

3 Make sure that the modem is off and that the AED is turned off for at least 60 seconds.

4 At the local site, connect the equipment as shown in Figure 4-4.
- Connect the modem cable to the AED and the modem.
- Connect the telephone cord to the modem and the analog telephone line.
- Connect the modem power cord or power adapter to a power source (if required).

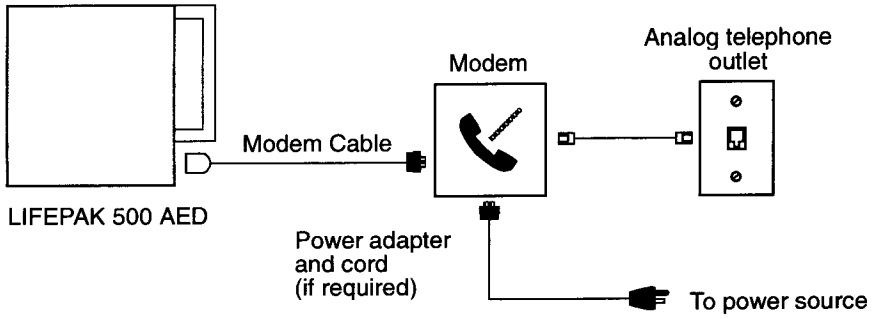


Figure 4-4 Equipment connections for data transfer by modem

5 Turn on the modem.

6 Press ON/OFF to turn on the AED. You will see:

BATTERY status message

SELF-TEST xx.xx message

7 After a few seconds, you will see the message:

TO SEND PUSH ▶

- Press ▶ to send the Current Patient.
- Press ▲ to send the Previous Patient.
- Press both ▶ and ▲ to send the Current and Previous Patients.

8 If the incident ID option is ON and an Incident ID has *not* already been entered for the Current or Previous Patient, you will see the message:

ENTER CURRENT [or PREVIOUS] ID?

YES

- Press ANALYZE (or the blank "menu" button) to answer YES; or
- Press ▲ to change to NO. Then press ANALYZE (or the blank "menu" button) and continue with step 10.

9 If you answered YES, you will see the message:

INCIDENT ID

XXXXXXXX

- Press ▲ to scroll through and select from the alphanumeric characters available.
- Press ▶ to advance to the next field.
- Repeat this process until the Incident ID is entered.
- Press ANALYZE (or the blank "menu" button) to accept the Incident ID.

Note: The last Incident ID entered will always be displayed.

10 Verify Incident ID entered. You will see the message:

XXXXXXXXX

OK TO SEND? YES

- Press ANALYZE (or blank "menu" button) to accept and send the Incident ID.
- Press ▲ to change to NO.
- Press ANALYZE (or blank "menu" button) to return to Incident ID screen.
- Follow step 9 beginning with bulleted items to change the Incident ID.

11 After ANALYZE (or the blank "menu" button) is pressed, the AED transfers the patient data. While the data is being transferred, the AED displays the following message to indicate progress:

SENDING

XX%COMPLETE

After the AED successfully completes the data transfer, it displays the SEND COMPLETE message.

12 After the AED displays the SEND COMPLETE message, check that the low battery indicator is not displayed.

13 Turn off the AED and prepare it for the next patient use.

Note: If you leave the LIFEPAK 500 AED unattended during data transfer, the AED automatically turns off after 15 minutes of no activity (after data transfer completed).

If the AED turns off, check the data transfer status:

1 Leave the data cable connected to AED and modem.

2 Turn on AED and look for the SEND COMPLETE message. If the CANNOT SEND message appears, refer to Table 6-2 on page 6-3 for troubleshooting tips.

3 If the SEND COMPLETE message appears:
- Check that the low battery indicator is not displayed.
- Disconnect the data transfer cable.

4 Turn off the AED and prepare it for the next patient use.

Troubleshooting During Data Transfer

If you cannot transfer data, refer to Table 6-2 on page 6-3 for troubleshooting tips.

SENDING DATA TO A COMPUTER BY DIRECT CONNECTION

These paragraphs describe the resources, equipment connections, and procedures required to send AED data to a computer by direct connection.

Required Resources

Table 4-3 summarizes the resources required to send data to a computer by direct connection.

Table 4-3 Required Resources for Sending Data to a Computer by Direct Connection

DESCRIPTION
PC Cable (for use with the LIFEPAK 500 AED)
Personal Computer: - QUIK-VIEW 500 data review program or CODE-STAT Suite data management system. - Microsoft Windows 3.1 or later for Data Transfer 500, and for QUIK-VIEW 500 if audio review is not needed. Microsoft Windows 95 for QUIK-VIEW 500 if audio review is needed. - Microsoft Windows 95 or Windows NT 4.0 for CODE-STAT Suite.

Procedure for Sending Data

Perform these steps to send the data:

1 Make sure that the AED is turned off for at least 60 seconds.
2 Connect the equipment as shown in Figure 4-5.
3 Make sure that the computer power is on and that the application program is open.
4 Press ON/OFF to turn on the AED. The CONNECT ELECTRODES message appears and remains until data transfer begins.

   The computer controls the data transfer. Refer to the application program operating instructions for information about data transfer commands. The AED will not display any status messages during the data transfer.

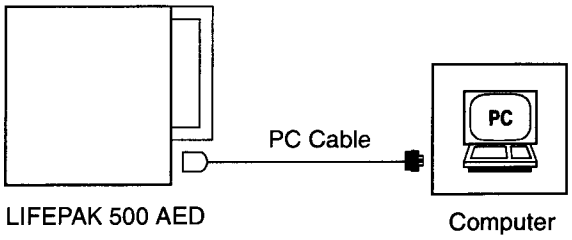


Figure 4-5 Equipment connections for data transfer by direct connection to a computer

5 When the computer is finished receiving data, do the following:
   • Check that the LOW BATTERY indicator is not displayed.
   • Disconnect the PC cable.
6 Turn off the AED and prepare it for the next patient use.

Note: If you leave the LIFEPAK 500 AED unattended during data transfer, the AED automatically turns off after 15 minutes of no activity (after data transfer completed).

If the AED turns off, check the data transfer status:

1 Check that the computer application program dialog box indicates that the patient record has been received. If the patient record has not been received, reinitiate procedure for sending data.
2 Turn on AED and check that the low battery indicator is not displayed.
3 Turn off the AED and prepare it for the next patient use.

Troubleshooting During Data Transfer

If you cannot transfer data, refer to the application program operating instructions for troubleshooting information.

SENDING DATA TO A PRINTER

These paragraphs describe the resources, equipment connections, and procedures required to print AED data on a printer.

Required Resources

Table 4-4 summarizes the resources required to print AED data.

Table 4-4 Required Resources for Printing Data

DESCRIPTION
Printer Cable (for use with the LIFEPAK 500 AED)
Printer (EPSON LX-300-compatible): - EPSON ESC/P protocol for 9-pin printheads - 25-pin D style connector

Procedure for Printing

Perform these steps to print AED data:

1 Make sure that the AED is turned off for at least 60 seconds.

2 Make sure that the printer is turned on.

3 While holding down the ▶ button, press ON/OFF to turn on the AED. Do not release the ▶ button until the AED displays:

BATTERY status message

SELF-TEST xx.xx message

4 Connect the equipment as shown in Figure 4-6.

- Connect the Printer Cable to the AED and the printer.

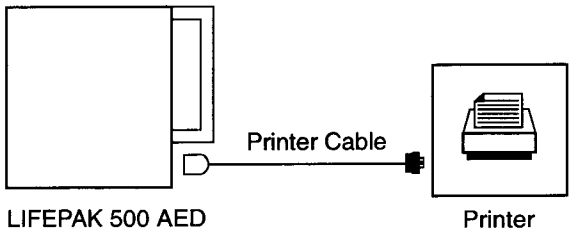


Figure 4-6 Connecting the AED to a printer

5 After a few seconds, you will see the message:

TO PRINT PUSH ▶

- Press ▶ to print the Current Patient.
- Press ▲ to print the Previous Patient.
- Press both ▶ and ▲ to print the Current and Previous Patients.

While the data is being transferred, the AED displays the following message to indicate progress:

SENDING

After the AED successfully completes the data transfer, it displays the SEND COMPLETE message.

6 Check that the LOW BATTERY indicator is not displayed.

7 Disconnect the Printer Cable.

8 Turn off the AED and prepare it for the next patient use.

Troubleshooting During Printing

If the data does not print, refer to Table 6-3 on page 6-4 for troubleshooting tips.

Examples of Printed Reports

The following pages present examples of printed reports:

- Figure 4-7, page 4-11 Event Log Report and Event Log Summary
- Figure 4-8, page 4-12 CODE SUMMARY Report
- Figure 4-9, page 4-15 Test Log Report

You cannot modify the format of the reports that the AED sends directly to the printer.

Event Log Report

This report lists all of the events that occurred during a patient use. The clock time and elapsed time are listed for each event. The box at the top of the report includes device and patient information. Some of the entries, such as the patient ID and name, are always blank for reports printed directly from the AED. (If you send AED data to a computer, the Data Transfer 500 program, QUIK-VIEW 500 data review program, or CODE-STAT Suite data management system allows you to fill in the blank spaces with information.)

Event Log Summary

This report summarizes important events for a particular patient record.

CODE SUMMARY Report

This report includes the ECG segments associated with key events such as analysis or shock.

Test Log Report

This report lists the time and results of the Auto Tests (AUTO TEST) and Test Load Tests (MANUAL TEST). If a test fails, the report lists fault codes that can help authorized service personnel troubleshoot and repair the AED.

Event Log Report

Incident ID No:	Patient ID No:
Incident Date: 15MAY98	Patient Name:
Operator ID No:	Age
Device Type: LIFEPAK 500	Sex:
Device Serial No: 00001203	Race:
Device ID: RFD#6	Software REV: 3005360-000 REV. 4.4
25mm/SEC, 1.0 cm/mV	Configuration: 000000000

00:00	09:47:08	POWER ON
01:07	09:48:15	PATIENT CONNECTED
01:07	09:48:15	"PUSH ANALYZE"
01:10	09:48:18	ANALYSIS 1
01:16	09:48:24	SHOCK ADVISED
01:25	09:48:33	"PUSH TO SHOCK"
01:25	09:48:33	SHOCK 1 - 200J
01:30	09:48:38	ANALYSIS 2
01:36	09:48:44	NO SHOCK ADVISED
01:39	09:48:47	CPR PROMPT
02:39	09:49:47	"PUSH ANALYZE"
03:03	09:50:11	CHECK PATIENT
03:03	09:50:11	"PUSH ANALYZE"
03:05	09:50:13	ANALYSIS 3
03:11	09:50:19	SHOCK ADVISED
03:21	09:50:29	"PUSH TO SHOCK"
03:36	09:50:44	CHARGE REMOVED
03:40	09:50:48	ANALYSIS 4
03:46	09:50:54	NO SHOCK ADVISED
03:47	09:50:55	CPR PROMPT
03:52	09:51:00	LOW BATTERY
04:10	09:51:18	BATTERY REMOVED
04:43	09:51:51	POWER ON
04:43	09:51:51	BATTERY REPLACED
04:47	09:51:55	"PUSH ANALYZE"
04:50	09:51:58	ANALYSIS 5
04:52	09:52:00	POWER OFF

Event Log Summary

01:10	FIRST ANALYSIS
01:25	FIRST SHOCK
	1 SHOCK DELIVERED

Comments: _____

_____

_____

_____

END OF REPORT PAGE 1

Figure 4-7 Example of Event Log Report and Event Log Summary

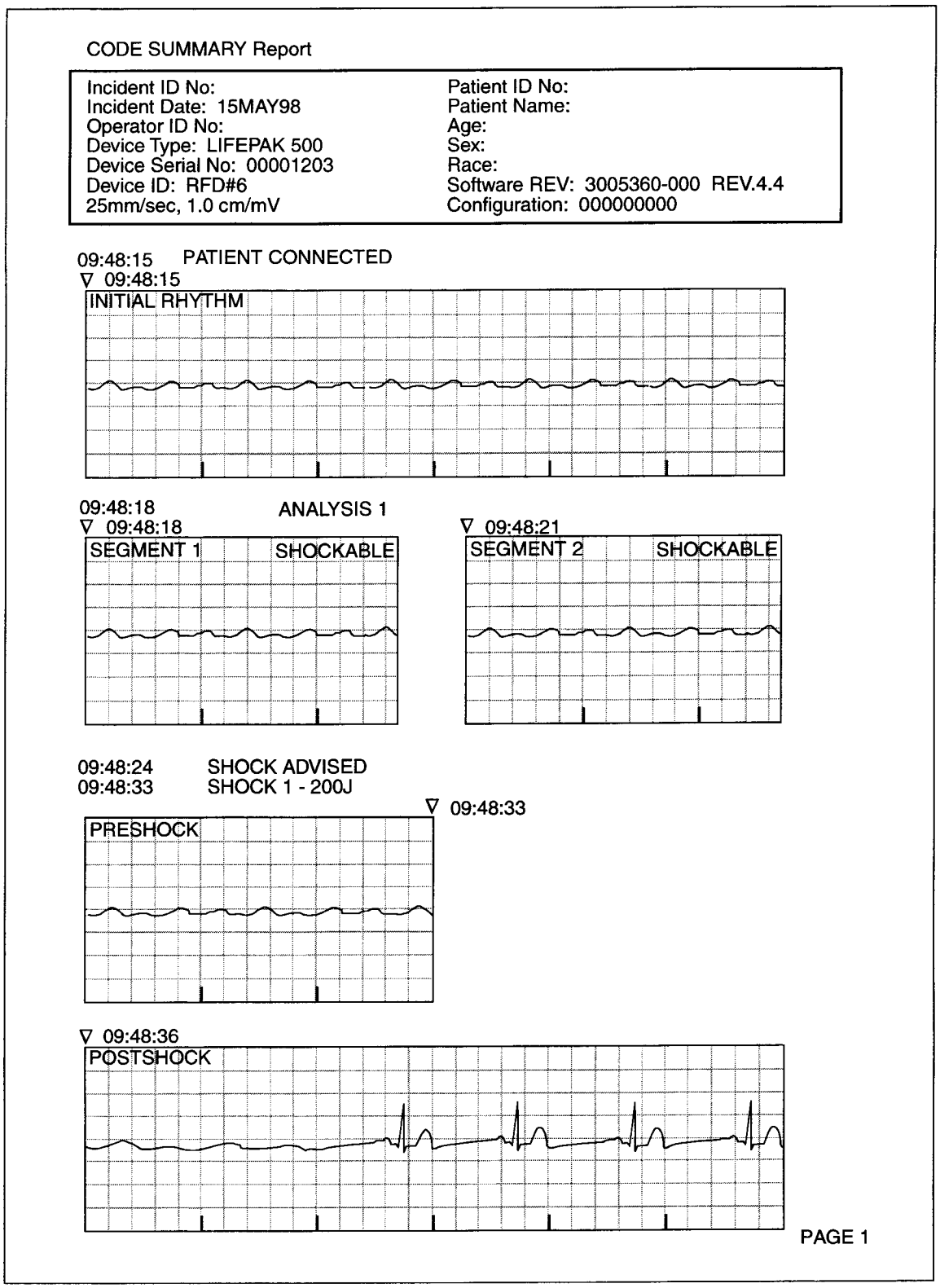


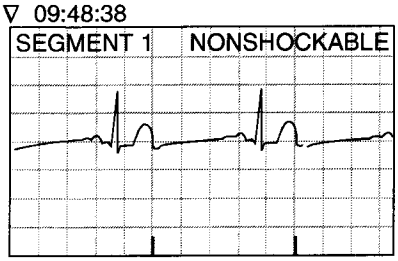
Figure 4-8 Example of CODE SUMMARY Report

CODE SUMMARY Report

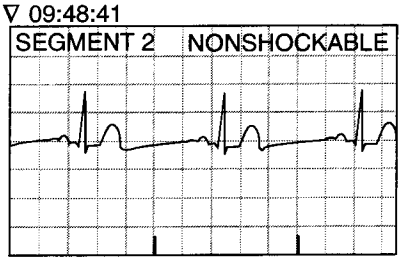
Incident ID No:	Patient ID No:
Incident Date: 15MAY98	Patient Name:

09:48:38 ANALYSIS 2

∇ 09:48:38



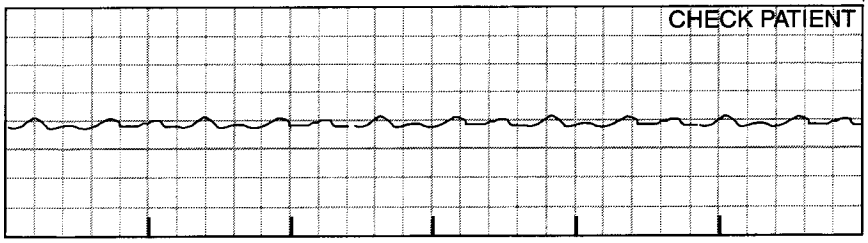
∇ 09:48:41



09:48:44 NO SHOCK ADVISED

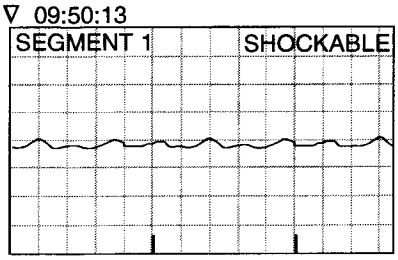
09:50:11 CHECK PATIENT

∇ 09:50:11

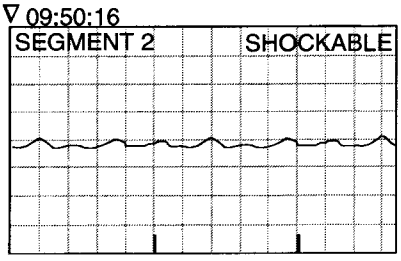


09:50:13 ANALYSIS 3

∇ 09:50:13



∇ 09:50:16



09:50:19 SHOCK ADVISED

09:50:44 CHARGE REMOVED

PAGE 2

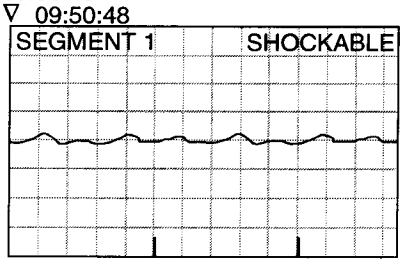
Figure 4-8 Example of CODE SUMMARY Report (cont.)

CODE SUMMARY Report

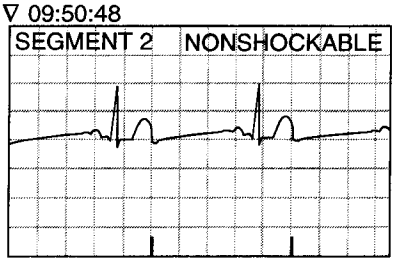
Incident ID No:	Patient ID No:
Incident Date: 15MAY98	Patient Name:

09:50:45 ANALYSIS 4

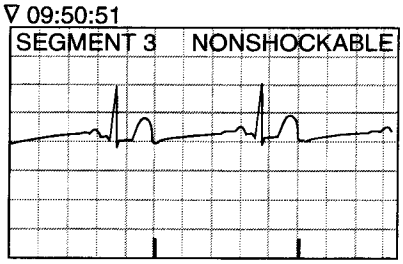
∇ 09:50:48



∇ 09:50:48



∇ 09:50:51



09:50:54 NO SHOCK ADVISED
09:51:58 ANALYSIS 5

END OF REPORT

PAGE 3

Figure 4-8 Example of CODE SUMMARY Report (cont.)

Test Log Report

Device Type: LIFEPAK 500	Software REV: 3005360-000 REV .4.4
Device Serial No: 00001203	Configuration: 000000000
Device ID: RFD#6	

Test History Log:

28 APR 96 03:00:12	AUTO TEST: PASS
28 APR 96 08:30:41	SELF TEST: PASS
29 APR 96 03:00:09	AUTO TEST: PASS
03 APR 96 03:00:09	AUTO TEST: PASS
01 MAY 96 03:00:09	AUTO TEST: PASS
02 MAY 96 03:00:09	AUTO TEST: PASS
03 MAY 96 03:00:09	AUTO TEST: PASS
04 MAY 96 03:00:09	AUTO TEST: PASS
05 MAY 96 03:00:09	AUTO TEST: PASS
05 MAY 96 08:27:10	SELF TEST: PASS
06 MAY 96 03:01:40	AUTO TEST: PASS
07 MAY 96 03:00:09	AUTO TEST: PASS
08 MAY 96 03:00:09	AUTO TEST: PASS
09 MAY 96 03:00:09	AUTO TEST: PASS
10 MAY 96 03:00:09	AUTO TEST: PASS
11 MAY 96 03:00:09	AUTO TEST: PASS
12 MAY 96 03:00:09	AUTO TEST: PASS
12 MAY 96 08:30:42	SELF TEST: PASS
13 MAY 96 03:00:09	AUTO TEST: PASS
14 MAY 96 03:00:09	AUTO TEST: PASS
15 MAY 96 03:00:09	AUTO TEST: PASS
16 MAY 96 03:00:09	AUTO TEST: PASS
17 MAY 96 03:00:09	AUTO TEST: PASS
18 MAY 96 03:00:09	AUTO TEST: PASS
19 MAY 96 03:00:09	AUTO TEST: PASS
19 MAY 96 08:30:40	SELF TEST: PASS
20 MAY 96 03:00:09	AUTO TEST: PASS
21 MAY 96 03:00:09	AUTO TEST: PASS
22 MAY 96 03:00:09	AUTO TEST: PASS
23 MAY 96 03:00:09	AUTO TEST: PASS

Major Fault Log:
No entries found

Minor Fault Log:
No entries found

END OF REPORT

PAGE 1

Figure 4-9 Example of Test Log Report

MAINTENANCE

This section describes how to perform operator-level maintenance and testing on the LIFEPAK 500 automated external defibrillator (AED). For troubleshooting information, refer to page 6-2. Topics in this section include:

Maintenance and Testing Scheduling	page 5-2
Inspection	5-3
Cleaning	5-4
Testing	5-4
Battery Maintenance	5-8
Electrode Storage	5-13
Service and Repair	5-13
Warranty	5-13
Supplies, Accessories, and Training Tools	5-14
Specifications	5-15
Clinical Summary	5-19

MAINTENANCE AND TESTING SCHEDULING

The LIFEPAK 500 AED performs an automatic self test every 24 hours. If the automatic self test detects a low battery condition or a condition that requires service, the AED activates an alarm. It is important to place the AED where the alarm is likely to be heard and to periodically inspect the AED.

The AED also performs a self test every time you turn on the AED. These self-tests do not eliminate the need for regular maintenance. You should do the following on a regular basis and after each time the AED is used:

- Inspect the AED as described in Table 5-1.
- Clean the AED as described in Table 5-2.
- Check to make sure that all necessary supplies and accessories (such as properly-maintained batteries and therapy electrodes) are readily accessible.

When establishing your local operator maintenance schedule, consider how often the AED is used and how familiar the operators are with AED operation. For example:

- If the AED is used on a weekly basis, daily inspections may be appropriate.
- If the AED is used on a monthly basis, weekly inspections may be appropriate.
- If the AED is used very infrequently, such as once a year, monthly inspections may be appropriate.

INSPECTION

Routinely inspect all devices, accessories, and cables by following the instructions in Table 5-1.

Table 5-1 LIFEPAK 500 AED Inspection

Instruction	Inspect for	Recommended Corrective Action
Examine the AED case, connector, battery well, battery pins, and accessories.	Foreign substances.	Clean the device as described in Table 5-2.
	Damage or cracks.	Contact authorized service personnel to troubleshoot and repair parts.
	Battery pins bent or discolored.	Contact authorized service personnel to replace or repair parts.
	Expired batteries or defibrillation electrodes.	Replace.
AEDs with Readiness Display: Observe Readiness Display	OK	None needed.
	Battery indicator displayed	Replace battery immediately.
	Service indicator displayed	Contact authorized service personnel to replace or repair parts.
AEDs without a Readiness Display: With the battery installed, press ON/OFF to turn on the AED.	BATTERY OK SELF-TEST xx.xx message.	None needed.
	Illumination and display of each LED, all indicators, and all LCD segments.	Contact authorized service personnel to repair or replace parts.
	BATTERY LOW or REPLACE BATTERY SELF-TEST xx.xx message.	Replace the battery immediately.
	Service indicator  or CALL SERVICE message.	Contact authorized service personnel to troubleshoot and repair the device.

Instruction	Inspect for	Recommended Corrective Action
Examine accessory cables.	Foreign substances.	Clean the cables as described in Table 5-2.
	Bend and flex the cable and inspect for cracks, damage, extreme wear, broken or bent connectors and pins.	Replace damaged or broken parts.
	Confirm that connectors engage securely.	Replace damaged or broken parts.

CLEANING

Clean the LIFEPAK 500 AED and accessories as described in Table 5-2. Use only the cleaning agents listed in the table.

CAUTION!

Possible equipment damage.

Do not clean any part of the AED or accessories with bleach, bleach dilution, or phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the LIFEPAK 500 AED or accessories.

Table 5-2 Recommended Cleaning Methods

Items	Cleaning Practice	Recommended Cleaning Agent
LIFEPAK 500 AED case, display, crevices, and accessories	Clean with damp sponge or cloth.	• Quaternary ammonium compounds • Rubbing (isopropyl) alcohol • Peroxide (peracetic acid) solutions

TESTING

This section describes the AED automatic self tests and the test load test. If testing indicates a problem, refer to Troubleshooting on page 6-2. If you cannot correct the problem, remove the AED from active service and contact authorized service personnel.

The AED stores the results of autotests and the external test load test in a Test Log. For information about retrieving Test Log data, refer to page 4-4.

Service Indicator and Message

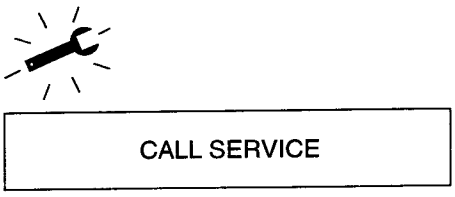
The service indicator appears if the automatic self-test detects a problem that requires service.

 ——————— Service indicator appears on the Readiness Display and on the key panel

If the service indicator appears on the key panel (but not flashing), you can still use the AED if it is needed for patient therapy. However, you should contact authorized service personnel to correct the problem as soon as possible. The service indicator will display until the problem is corrected.

If the automatic self-test detects a problem that requires immediate service (such as a malfunctioning charging circuit), the service indicator appears on the Readiness Display, the service indicator on the key panel flashes, and the CALL SERVICE message appears.

Readiness Display on device handle



Display on Key Panel

Turn the AED off and on. If the CALL SERVICE message disappears, you can still use the AED if it is needed for patient therapy. However, you should contact authorized service personnel to correct the problem as soon as possible. If the CALL SERVICE message reappears, the service indicator on the device key panel will continue to flash and the message will remain on. Contact authorized service personnel immediately to correct the problem. You should not use the AED until the problem is corrected.

Power-On Self-Test

Whenever the AED is turned off for at least 60 seconds and then turned on, the AED performs a "cold start." During a cold start, the AED performs internal self-tests to check that internal electrical components and circuits work properly. During the self-test, the AED displays the following messages:

MEDTRONIC PHYSIO-CONTROL c1999	
BATTERY OK SELF-TEST xx.xx	The xx.xx is the software version installed.

If the AED requires service, the service indicator appears. Contact authorized service personnel to perform service.

Note: If the battery has been adequately charged to deliver therapy, you will see OK on the Readiness Display and the BATTERY OK message on the LCD during the self-test. If the battery is low, you will see a battery indicator on the Readiness Display, an illuminated battery indicator on the device key panel, and the LOW BATTERY message on the LCD. When the LOW BATTERY message first appears, the device will provide eleven or more shocks for a nonrechargeable battery and six or more shocks for a rechargeable battery. If the battery is very low, the REPLACE BATTERY message displays and the battery indicator on the key panel flashes. When the REPLACE BATTERY message first appears, the device will provide three or more shocks.

Auto Tests

The AED periodically performs auto tests. During an auto test, the AED displays the following message:

BATTERY OK SELF-TEST xx.xx

If the AED detects a problem during an auto test that requires service but does not prevent AED use, it displays the service indicator the next time you turn on the AED.

If the AED detects a problem during an auto test that requires immediate service, it activates an intermittent, audible alarm.

Note: It is important that when the AED is stored with the battery installed, temperature exposure should not fall below 0°C (+32°F) or exceed 50°C (+122°F). If the AED is stored outside this temperature range, the auto tests may erroneously detect a problem and the AED may not operate properly.

Daily Auto Test

Every day at 0300 (3:00 am) the AED automatically performs the following tasks:

- Turns itself on (the ON/OFF LED illuminates briefly).
- Performs self-test (SELF-TEST message displays).
- Stores the results in the Test Log.
- Turns itself off.

On a regular basis, the Daily Auto Test will test for low or replace battery conditions.

The Daily Auto Test is not performed if the AED is already turned on at 0300 or if the battery is not installed. If the AED is turned on while the Daily Auto Test is in progress, the test is halted; the AED will turn on normally.

Extended Auto Test

The AED automatically turns on and performs the Extended Auto Test on a regular basis at 0300. In the Extended Auto Test, the AED performs the following tasks:

- Turns itself on (the ON/OFF LED illuminates briefly).
- Performs Extended Self-test (SELF-TEST message displays).
- Stores the results in the Test Log.
- Turns itself off.

To use the AED when the Extended Auto Test is in progress, push ON or connect the electrodes to the patient. The test will be halted and the AED will operate normally. The Extended Auto Test is not performed if the AED is already turned on at 0300 or if the battery is not installed.

External Test Load Test

The external test load test checks the AED charging circuits and the operator's response during a typical ECG analysis and charging cycle. During this test, the AED charges for a low energy test shock. The usual messages and audio prompts are provided.

To perform the test load test:

1 Make sure that the AED is turned off.

2 Connect the Physio-Control test load to the cable connector on the AED.

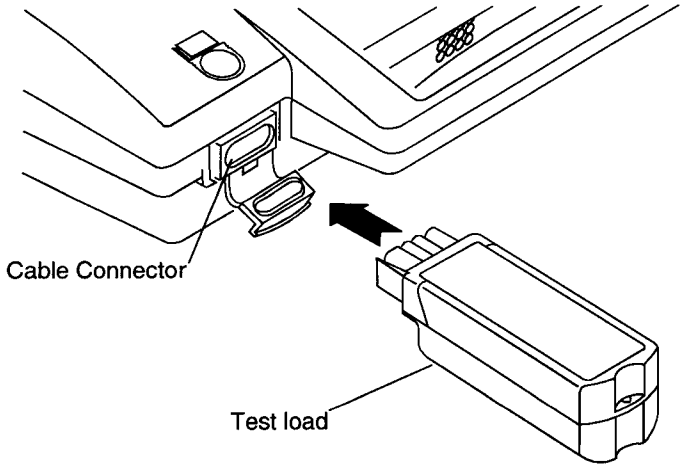


Figure 5-1 Test load connection

3 Press ON/OFF and observe that the TEST MODE message appears. (The TEST MODE message is displayed throughout the test.) If the TEST MODE message does not display, reconnect the test load and try again. If AUTO ANALYZE is off or AUTO ANALYZE 1 is selected, you will see and hear:

PUSH ANALYZE message

PUSH ANALYZE voice prompt

4 Press ANALYZE. If AUTO ANALYZE 2 is selected or you have an AED that does not have an ANALYZE button, the AED will start analyzing automatically.
You will see and hear:

ANALYZING NOW and STAND CLEAR messages

ANALYZING NOW, STAND CLEAR voice prompts

After a few seconds you will see and hear:

SHOCK ADVISED message

SHOCK ADVISED voice prompt

A rising charging tone that simulates a typical charge time

5 When the AED is fully charged, you will see and hear:

STAND CLEAR and PUSH TO SHOCK messages

STAND CLEAR and *PUSH TO SHOCK* voice prompts

6 Press SHOCK to discharge the energy into the test load.

7 Confirm that the AED displays the TEST OK message.

8 Disconnect the test load.

9 Press ON/OFF to turn off the AED.

10 Prepare the AED for the next patient use.

After the test is complete, the AED records the results in the Test Log. If the AED detects a problem during the test, the service indicator and CALL SERVICE message appear. Contact authorized service personnel to perform service. To repeat the test, turn off the AED and then turn it on again.

BATTERY MAINTENANCE

The LIFEPAK 500 AED can be powered by two types of batteries:

- LIFEPAK 500 nonrechargeable lithium battery pak
- LIFEPAK 500 rechargeable SLA (Sealed Lead-Acid) battery pak

Either type of battery may be installed. Follow the guidelines described in this section to help maximize battery life and performance. Use only Physio-Control Battery Pak batteries with the LIFEPAK 500 AED.

WARNINGS!

Possible AED shutdown.

When the LIFEPAK 500 AED displays the REPLACE BATTERY message, replace the battery immediately.

Possible loss of power during patient care.

Using an improperly-maintained battery to power the AED may cause power failure without warning. Maintain batteries as described in these Operating Instructions.

Note: When a battery is removed from the AED, battery and service indicators appear on the Readiness Display. After replacing the battery, turn on the device to reset the Readiness Display.

Nonrechargeable Battery Pak

The nonrechargeable lithium battery pak requires less maintenance than the rechargeable SLA battery pak since it never requires recharging. With the lithium battery pak installed, the LIFEPAK 500 AED automatically tests it as part of the Daily Auto Test. The AED also performs the battery test during each charge/discharge cycle and the first time the AED is turned on after a new battery has been installed.

To check the battery level, turn on the AED for at least 10 seconds and look for the BATTERY status message during the self-test. If there is no message, turn off the AED for at least one minute and then turn it on again. The battery status message should display following the self-test. Do not check the status of more than two lithium or three SLA batteries within a 15-minute period. The AED may not accommodate more frequent battery checks.

When optimally maintained, a new lithium battery has a capacity of 7.5 Amp hours, which is equivalent to 14 hours of "on time" *or* 312 discharges. Just turning the AED on ("on time") uses up battery capacity. Each year, battery capacity decreases while the battery is in the AED because of the battery's normal self-discharge rate and the energy used by the AED auto tests. Figure 5-2 shows the expected capacity of the lithium battery over 5 years as a result of AED auto tests and battery self-discharge only. For example, after 4 years with no patient use of the AED, approximately 40% of the useful life of the battery remains (8.4 hours of "on time" or 187 discharges). Any patient use of the AED, "on time" and shocks, will reduce the battery's useful life further.

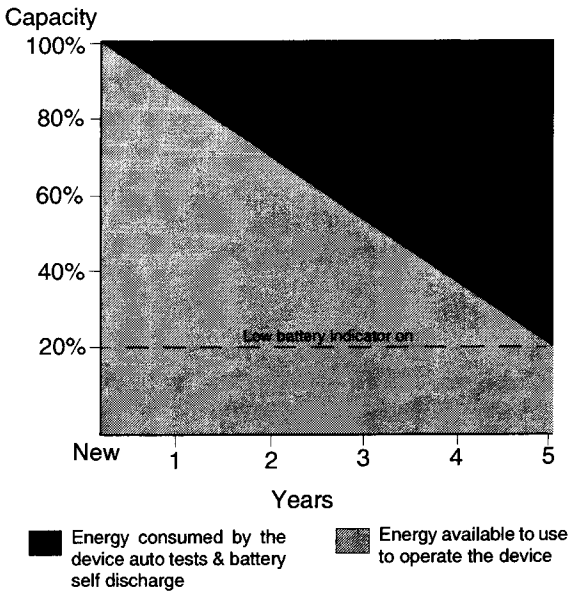


Figure 5-2 Lithium battery capacity over 5 years while installed in a LIFEPAK 500 AED at 20°C (68°F)

A new lithium battery pak has a shelf life of 5 years if stored at the proper temperature. Although a lithium battery may be stored for up to 5 years, it self-discharges over time. Therefore, when the battery is eventually placed in the AED, its useful life will be reduced depending on how long it "sat on the shelf."

To properly maintain nonrechargeable lithium battery paks:

- Do not attempt to recharge (lithium battery paks cannot be connected to the battery charger used to recharge the rechargeable SLA battery paks).
- Do not use beyond the expiration date marked on the battery label.
- Do not expose to temperatures greater than +50°C (+122°F).
- Do not allow electrical connection between the battery contacts.

WARNING!

Possible explosion, fire, or noxious gas.

Attempting to recharge a LIFEPAK 500 nonrechargeable lithium battery pak can cause an explosion or fire or release noxious gas. Dispose of expired or depleted lithium battery paks as described in these Operating Instructions.

CAUTION!

Possible battery damage.

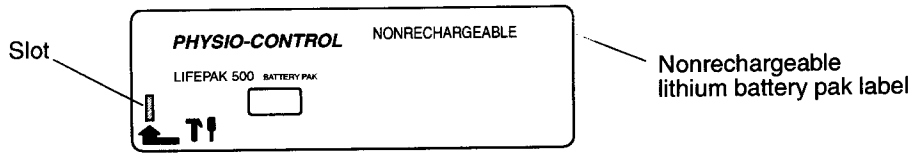
Electrical connection between battery contacts can blow an internal fuse and permanently disable the battery.

Discharging Nonrechargeable Batteries

Before disposing of lithium battery paks, make sure that they are fully discharged. To discharge a lithium battery pak, follow this procedure:

1 Place the battery pak with the label side up on a firm, flat surface such as a table top or floor.

2 Locate the small slot on the corner marked by the arrow:



3 Place the tip of a flat-tipped screwdriver on the slot.

4 Using a hammer, strike a moderate blow straight down on the top of the screwdriver handle. Make sure that the tip of the screwdriver breaks the label and penetrates approximately 3mm (1/8 inch). This will strike an internal pin, initiate full discharge, and permanently disable the battery.

5 Set the battery pak aside. Wait for at least 1 week to make sure that the battery pak is fully discharged before disposing.

Disposing of Nonrechargeable Batteries

After fully discharging a lithium battery pak as described previously, dispose of the battery pak. Follow your national, regional, and local regulations for disposal. Contact a local Medtronic Physio-Control representative for more information.

In the US, Environmental Protection Agency and Department of Transportation regulations allow disposal of lithium batteries with ordinary household waste **provided that they are fully discharged.** Be sure to comply with any other local or regional regulations before disposal. For more information or assistance, contact your local Medtronic Physio-Control representative or call 1.800.442.1142.

Rechargeable Battery Pak

The rechargeable SLA battery pak requires more maintenance than a lithium battery pak since it must be recharged periodically. The SLA battery pak should be recharged monthly or after each use. SLA battery paks are most appropriate when the LIFEPAK 500 AED is used on a frequent basis and for those who use the AED with a simulator for training. With an SLA battery pak installed, the LIFEPAK 500 AED automatically turns on to test it as part of the Extended Auto Test. To check the battery level, turn on the AED and look for the BATTERY OK message during the self-test.

When optimally maintained, a new SLA battery pak can provide approximately 3 hours of "on time" *or* 59 discharges during 3 months of use without recharging the battery. Just turning the AED on ("on time") uses up battery capacity. Each month, battery capacity decreases while the battery is in the AED because of the battery's normal self-discharge rate and the energy used by the AED self-tests. Figure 5-3 shows the expected capacity of the SLA battery pak without recharging over 3 months as a result of AED self-tests and battery self-discharge only. For example, after one month with no patient use of the AED, approximately 20% of the useful life of the battery has been depleted. Any patient use of the AED ("on time" and shocks) will reduce the capacity further. Even when properly maintained, SLA battery paks should be replaced every two years or after 200 charge cycles, whichever comes first.

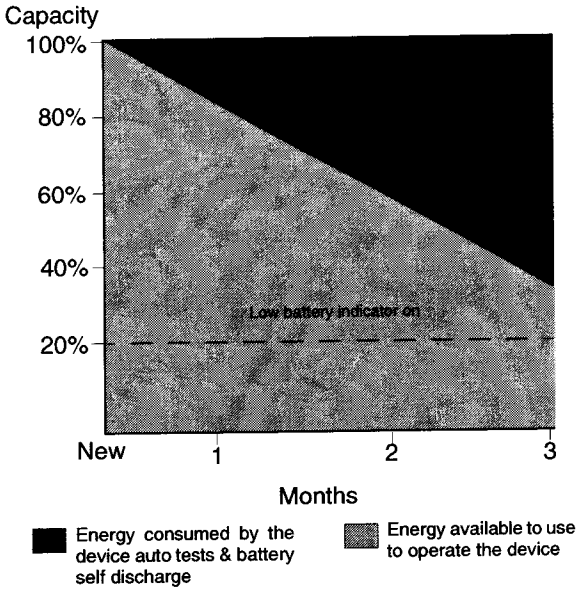


Figure 5-3 SLA battery capacity while installed in a LIFEPAK 500 AED for 3 months without recharging at 20°C (68°F)

To properly maintain SLA battery paks:

- Recharge after each use or once a month, whichever comes first. Maintain a battery recharge record.
- Use only the Physio-Control battery charger designed for use with the LIFEPAK 500 AED. Do not use any other charger.
- Recharge until the battery charger charge LED is green. This indicates that the battery charger has completed the fast-charge cycle. Undercharging can cause battery damage.
- Recharge only at temperatures between +15°C and +35°C (+59°F and +95°F).
- Never expose battery paks to temperatures greater than +50°C (+122°F).
- Battery paks are best when used and stored between 0°C and 35°C (32°F and 95°F). Higher temperatures accelerate the loss of charge and wear out the battery pak sooner. Lower temperatures reduce battery capacity.
- Do not allow electrical connection between the battery contacts.

WARNINGS!

Possible loss of power during patient care.

Stored batteries lose charge. Failure to charge a rechargeable battery before use may cause device power failure without warning. Always charge a stored battery before placing it in active use.

Possible loss of power during patient care.

Using an improperly maintained battery to power the defibrillator may cause power failure without warning. Use the LIFEPAK 500 battery charger to charge the rechargeable battery pak.

CAUTIONS!

Possible battery damage.

Recharge the battery until the battery charger charge LED is green. Undercharging can cause battery damage.

Possible battery damage.

Charging batteries outside the temperature range of +15°C to +35°C (+59°F to +95°F) may cause improper charging and shorten battery life.

Possible battery damage.

Electrical connection between battery contacts can blow an internal fuse and permanently disable the battery.

Recharging a Rechargeable Battery Pak

The battery charger fully charges a connected SLA battery in about 10 hours. The battery charger applies a high-level, fast charge for the first 10 hours that the battery is connected. If the battery remains connected, the battery charger applies a low-level trickle-charge to maintain a full charge. Agency approval markings are provided on the bottom of the battery charger.

To charge a battery:

1 Connect the battery charger to an appropriate ac power source (100 to 240Vac, 50 or 60Hz). The green LED (marked by the ▌ symbol) appears when the power is connected.

2 Connect the battery to the battery charger.

3 Confirm that the charge LED (marked by the ϟ symbol) is amber. This indicates that the battery charger is applying a fast charge.

4 Wait at least 10 hours. Then, confirm that the charge LED is green. The green LED indicates that the fast-charge cycle is complete and the battery is receiving a trickle-charge to maintain full charge.

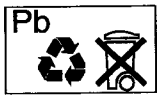
5 Disconnect the battery.

A fully charged battery is not harmed if it remains connected to the battery charger. However, if a battery is disconnected and then reconnected, the battery charger begins the 10 hours of fast charge again. Additional battery charge cycles without discharging can reduce battery life.

Recycling Rechargeable Batteries

Recycle SLA battery paks locally according to national, regional, and local governmental regulations. If recycling is not possible, contact a Medtronic Physio-Control representative for information or assistance. In the US, call 1.800.442.1142.

To promote awareness of battery recycling, SLA battery paks are marked with this label:



ELECTRODE STORAGE

For information about defibrillation electrode storage, refer to the operating instructions for the FAST-PATCH and QUIK-COMBO electrodes.

SERVICE AND REPAIR

WARNING!

Shock hazard.

Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.

If the LIFEPAK 500 AED requires service as indicated by testing, troubleshooting, or the service indicator, contact authorized service personnel. In the US, call Medtronic Physio-Control Technical Support at 1.800.442.1142. When you call Medtronic Physio-Control to request service, provide the following information:

- Model number and part number
- Serial number
- Observation of the problem that led to the call

If the device must be shipped to a service center or the factory, pack the device in the original shipping container. If this is not possible, ship the device in protective packing to prevent shipping damage.

The *LIFEPAK 500 AED Service Manual* provides detailed technical information to support service and repair by authorized service personnel.

Product Recycling Information

Recycle the device at the end of its useful life.

- **Recycling Assistance**
  The device should be recycled according to national and local regulations. Contact your local Medtronic Physio-Control representative for assistance.
- **Preparation**
  The device should be clean and contaminant-free prior to being recycled.
- **Recycling of Disposable Electrodes**
  After disposable electrodes are used, follow your local clinical procedures for recycling.
- **Packaging**
  Packaging should be recycled according to national and local regulations.

WARRANTY

Refer to the product warranty statement included in the accessory kit shipped with the product. For duplicate copies, contact your local Medtronic Physio-Control representative. In the US, call 1.800.442.1142.

SUPPLIES, ACCESSORIES, AND TRAINING TOOLS

Table 5-3 lists supplies, accessories, and training tools for the LIFEPAK 500 AED. For information about ordering, contact your local Medtronic Physio-Control representative. In the US, call 1.800.442.1142.

Table 5-3 Supplies, Accessories, and Training Tools

Description	Part Number
LIFEPAK 500 nonrechargeable lithium battery pak	3005380
LIFEPAK 500 rechargeable SLA battery pak	3005379
QUIK-COMBO pacing/defibrillation/ECG electrodes with REDI-PAK preconnect system	3008497
QUIK-COMBO pacing/defibrillation/ECG electrodes LLW (3.5 ft) (1.07m)	3008826
QUIK-COMBO pacing/defibrillation/ECG electrodes (2 ft lead wire)	806086
QUIK-COMBO defibrillation cable	3011215
LIFEPAK 500 battery charger	3006535
Physio-Control Test Load	3005389
QUIK-COMBO Patient Simulator	803499-09
FAST-PATCH defibrillation cable kit	3010699
FAST-PATCH disposable defibrillation/ECG electrodes	3006292
Physio-Control Patient Simulator (For use with FAST-PATCH defibrillation cable.)	803499-00
CODE-STAT Suite data management system	3011520
Data Transfer 500 information management program	3005332
QUIK-VIEW 500 data review program	3005335
LIFEPAK 500 Carrying Case	3005343
LIFEPAK 500 Electrode Storage Tray kit	3010697
AED Instruction Card	3011111
LIFEPAK AED TRAINER	3005578
AED TRAINER training electrodes	3006007
Wall mount bracket	3009767
Spare battery pouch kit	3010698
Cables:	
LIFEPAK 500 Printer Cable	3005381-002
LIFEPAK 500 Modem Cable	3005381-001
LIFEPAK 500 PC Cable	3005381-000
Setup Transfer Cable	3010779
Literature:	
LIFEPAK 500 AED Operating Instructions	3005338
LIFEPAK 500 AED Service Manual	3005339
Defibrillation: What You Should Know	805662
Training and Implementation Guide for use with the LIFEPAK 500 automated external defibrillator	3011020
AED Challenge Interactive Computer Training Tool	3011019-000

SPECIFICATIONS

Table 5-4 lists the specifications for the LIFEPAK 500 AED (monophasic and biphasic).

Table 5-5 lists the specifications for the LIFEPAK 500 AED Battery Charger.

Table 5-4 LIFEPAK 500 AED Specifications[1]

AED	
Input	ECG via QUIK-COMBO or FAST-PATCH disposable electrodes. Standard placement (anterior-lateral).
Electrical Protection	Input protected against high voltage defibrillator pulses per IEC 60601/ EN 60601.
Safety Classification	Internally powered equipment IEC 60601-1/EN 60601-1, 5.1.
Waveform	Monophasic pulse (Edmark) per AAMI DF2-1989, 3.2.1.5.1 Biphasic truncated exponential, with voltage and duration compensation for patient impedance.[2]
Output Energy Accuracy	±15% into 50 ohms (monophasic) ±10% into 50 ohms (biphasic) ±15% into 25 to 100 ohms (biphasic)
Output Energy Sequence	Monphasic: 200, 200, 360 joules (360 joules thereafter) or 200, 300, 360 joules (360 joules thereafter). Biphasic: Three levels, user configurable from 200 to 360 joules, delivered (Level 1, Level 2, Level 3, Level 3...).
Charge Time	With a new, nonrechargeable battery pak, or a new, fully charged rechargeable battery pak: 200 joules in less than 9 seconds 360 joules in less than 15 seconds.
Controls	
ON/OFF	Turns device power on or off.
ANALYZE	Starts ECG analysis. (Optional).
SHOCK	Delivers defibrillation energy. Active only when Shock Advisory System advises defibrillation.
Clock Set	Two switches ▲ and ▶ are provided to set the clock.
Display	Two-line, 20-character per line dot matrix liquid crystal display.
Readiness Display	Indicates OK when self-test completed successfully.
Low Battery Indicator	Low battery icon: At least 11 discharges remaining with nonrechargeable battery pak At least 6 discharges remaining with rechargeable battery pak.
Service Indicator	Service icon.
Displayed Messages	Messages prompt user through complete operating sequence.

Audible Tones	Coded tones assist user through device operation and alert operator of display messages.
Voice Prompts	Prompt user through complete operation sequence.

EVENT DOCUMENTATION

Type	Internal digital memory.
Memory Capacity	20 minutes audio recording (optional). ECG and event log of operator/device actions: At least 20 minutes if unit is configured with audio recording and audio recording setup option is ON. At least 80 minutes if configured with audio recording and audio recording setup option is OFF. At least 60 minutes if not configured with audio recording.
Report Types	CODE SUMMARY report, Event Log report, Test Log report.
Capacity	300 Event Log events. 30 Test Log device tests (assuming no fault codes).
Communications	Options: - Direct connection to personal computer - Modem connection to personal computer using Hayes AT-Compatible modem - Print direct with EPSON® ESC/P protocol for printers with 9-pin printheads.
Data Review	LIFENET™ system compatible. Options: - DATA TRANSFER™ 500 information management program - QUIK-VIEW™ 500 data review program - CODE-STAT™ Suite data management system, v 2.0 or above.

ENVIRONMENTAL

Operating Temperature	0° to +50°C* (+32° to +122°F).
Storage Temperature	-30° to +65°C* (-22° to +149°F) without battery and electrodes. -30° to +65°C* (-22° to +149°F) with battery and electrodes, maximum total exposure time limited to one week.
Atmospheric Pressure	760 to 429mmHg (0 to +15,000 ft above sea level).
Relative Humidity	10 to 95% (non-condensing).
Water Resistance	IEC 60529/EN 60529 IPX4 "Splash-proof" with electrodes or connector cover installed.

Shock	MIL-STD-810E, Method 516.4, Procedure 1 (40g, 6–9ms pulse, 1/2 sine each axis).
Vibration	Monophasic version: MIL-STD-810E, Method 514.4, Category 10 Biphasic version: MIL-STD-810E, Method 514.4, Helicopter - Category 6 (3.75 Grms) and Ground Mobile - Category 8 (3.15 Grms). RTCA D0 160C, Table 8-2 Fixed Wing - Turbojet Engine Classification C' (Fuselage). Test level per Figure 8-5 C'. One hour in each of three axes.
Aircraft	Tested to RTCA/DO-160C, "Environmental Conditions and Test Procedures for Airborne Equipment." (Details available on request.)

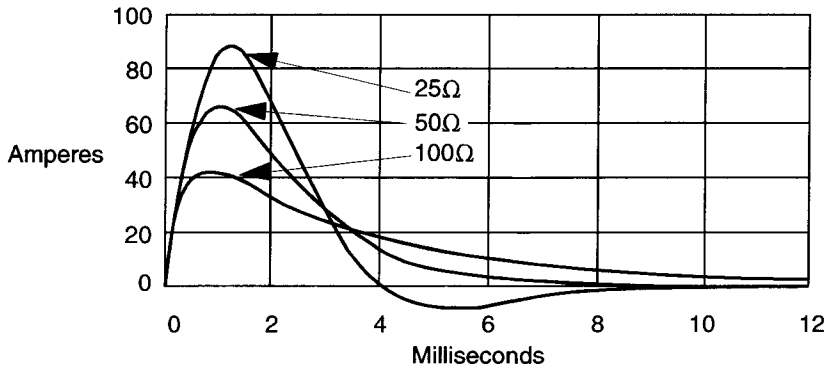
*__Note:__ See page 5-8 for information on caring for batteries.

GENERAL

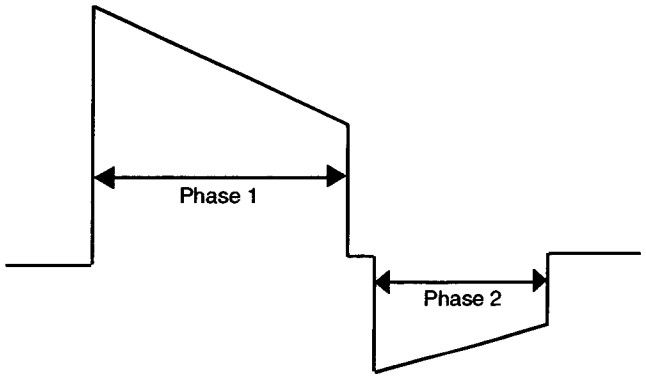
Rechargeable SLA battery pak	
Type	Sealed lead-acid, 8V, 2.5 amp hours.
Capacity	Typical: 59 full discharges or 3 hours of "on time" with a new, fully charged battery. Minimum: 43 full discharges with a new, fully charged battery.
Battery Charge Time	10 ±1 hours. Battery charging limited to +15° to +35°C (+59° to +95°F).
Recommended Replacement Interval	2 years or 200 battery charge/discharge cycles, whichever comes first using recommended battery maintenance procedures.
Weight	0.9kg (1.9lb).
Nonrechargeable lithium battery pak	
Type	Sealed lithium, 12V, 7.5 amp hours.
Certification	FAA: TSO – C97 or CAA: BS2G237.
Capacity	Typical: 312 full discharges or 14 hours of "on time" with a new battery. Minimum: 230 full discharges with a new battery.
Shelf Life	5 years (4 years for aircraft use).
Weight	0.5kg (1.2lb)
Physical Characteristics	
Height	10.2cm (4.0in)
Width	26.7cm (10.5in)
Depth	29.5cm (11.6in) including handle.
Weight	2.76kg (6.1lb) without battery or electrodes (monophasic) 2.41kg (5.3lb) without battery or electrodes (biphasic).
	Defibrillation protected, type BF patient connection.

DEFIBRILLATOR

Waveform — Monophasic pulse (Edmark) per AAMII DF2-1989



Waveform — Biphasic truncated exponential waveform



Patient Impedance (Ω)	Phase 1 Duration (ms) Min	Phase 1 Duration (ms) Max	Phase 2 Duration (ms) Min	Phase 2 Duration (ms) Max	Tilt (%) Min	Tilt (%) Max
25	5.1	6.0	3.4	4.0	74.8	82.9
50	6.8	7.9	4.5	5.3	63.9	71.0
100	8.7	10.6	5.8	7.1	50.7	56.5
125	9.5	11.2	6.3	7.4	46.3	51.6

[1]All specifications at 20°C (68°F) unless otherwise stated. All performance specifications assume the device has been stored (two hours minimum) at the operating temperature prior to operation.

[2]Specifications apply from 25 to 200 ohms. Voltage compensation is limited to the voltage that would result in delivery of 360 joules into 50 ohms.

Table 5-5 LIFEPAK 500 AED Battery Charger Specifications

GENERAL	
Safety Classification	⧈ Class II (double insulation), IEC 60601/EN 60601, 5.1
Input	100–240V 0.7–0.4A 50/60 Hz
Output	9.9Vdc for 10 hours, 9.2V trickle charge thereafter
Output Protection	Current limited, short circuit protected
ENVIRONMENTAL	
Operating Temperature	15°–35°C (50°–95°F)
Water Resistance	IEC 60529/EN 60529 IPX0 (Indoor Use Only)

CLINICAL SUMMARY

Background

Physio-Control conducted a multi-centered, prospective, randomized and blinded clinical trial of biphasic truncated exponential (BTE) shocks and conventional monophasic damped sine wave (MDS) shocks. Specifically, the equivalence of 200J and 130J BTE shocks to 200J MDS shocks was tested.

Methods

Ventricular fibrillation (VF) was induced in 115 patients during evaluation of implantable cardioverter defibrillator function and 39 patients during electrophysiologic evaluation of ventricular arrhythmias. After 19±10 seconds of VF, a customized defibrillator delivered an automatically randomized shock. Efficacy was based on success of this shock. To demonstrate equivalence of test shocks to control shocks, the 95% upper confidence limit of the difference in efficacy (95UCLD), control minus test, was required to be less than 10%.

Results

Ventricular Fibrillation

The efficacy of the 200J BTE shocks was demonstrated to be at least equivalent to the efficacy of 200J MDS shocks (95UCLD=2%). The difference is success rates of 200J MDS minus 200J BTE shocks was -10% (exact 95% confidence interval from -27% to +4%). The 130J BTE shocks were not demonstrated equivalent to 200J MDS shocks (95UCLD=22%). However, neither was their efficacy significantly lower than that of the 200J MDS shocks (statistical power limited by small sample sizes). For all shock types, hemodynamic parameters (oxygen saturation and systolic and diastolic blood pressure) were at or near their pre-induction levels by 30 seconds after successful shocks.

Shock	Ventricular Fibrillation 1st Shock Success	Exact 95% Confidence Interval
200J MDS	61/68 (90%)	80–96%
200J BTE	39/39 (100%)	91–100%
130J BTE	39/47 (83%)	69–92%

Ventricular Tachycardia

Seventy-two episodes of ventricular tachycardia (VT), induced in 62 patients, were treated with randomized shocks. High rates of conversion were observed with biphasic and monophasic shocks. Sample sizes were too small to statistically determine the relationship between success rates of the waveforms tested.

Shock	Ventricular Tachycardia 1st Shock Success	Exact 95% Confidence Interval
200J MDS	26/28 (93%)	77–99%
200J BTE	22/23 (96%)	78–100%
130J BTE	20/21 (95%)	76–100%

Conclusions

In this double-blinded study, the efficacy of the 200J BTE shocks was demonstrated to be at least equivalent to the efficacy of 200J MDS shocks for defibrillation of short duration, electrically-induced VF. However, the comparison of efficacy of 130J biphasic and 200J monophasic shocks for VF was inconclusive. All waveforms tested provided a high rate of termination of VT. The VT sample sizes were too small to statistically determine the relationship between VT success rates of the waveforms tested.

Compared to conventional shocks for VF, we found no positive or negative effect of biphasic shocks for VF on hemodynamic parameters following the defibrillating shock. It is possible that, compared to 200J monophasic shocks, 200J biphasic shocks will in some cases enable earlier termination of VF. Therefore, we conclude that biphasic shocks for VF delivered at conventional energy levels have the potential to improve outcome in resuscitation of patients with cardiac arrest.

TROUBLESHOOTING

This section describes how to troubleshoot LIFEPAK 500 automated external defibrillator (AED) operating problems. This section also describes screen messages, voice prompts, and event types.

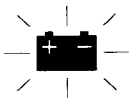
Troubleshooting During Patient Care	page 6-2
Troubleshooting During Modem Data Transfer	6-3
Troubleshooting During Printing	6-4
Troubleshooting During Setup Transfer	6-5
LIFEPAK 500 AED Screen Messages	6-5
LIFEPAK 500 AED Voice Prompts	6-7
LIFEPAK 500 AED Event Types	6-7

If you cannot correct the problem, follow these steps:

- Remove the AED from active service.
- Contact authorized service personnel for service and repair.

TROUBLESHOOTING DURING PATIENT CARE

Table 6-1 Troubleshooting During Patient Care

Observation	Possible Cause	Corrective Action
1 CONNECT ELECTRODES message appears.	Inadequate connection to AED.	• Check for complete insertion of connector to AED.
	Electrode does not adhere properly to the patient.	• Press electrodes firmly on patient's skin. • Clean, shave, and dry the patient's skin as recommended.
	Electrodes are dry, damaged, or out-of-date.	• Replace the electrodes.
2 MOTION DETECTED and STOP MOTION messages appear during analysis.	Patient movement.	• Stop CPR during analysis. • When patient is being manually ventilated, press ANALYZE after complete exhalation.
	Patient movement because of agonal respirations.	• Press ANALYZE immediately after exhalation or wait until agonal respirations are slower or absent.
	Electrical/radio frequency interference.	• Move hand-held communication devices or other suspected devices away from the AED when possible.
	Vehicle motion.	• Stop vehicle during analysis. • Move patient to stable location when possible.
3 LOW BATTERY  message or indicators appear on Readiness Display and key panel.	Low battery.	• If using AED, continue to use and replace battery at earliest convenience. Approximately 20% of battery energy remains. • If AED not in use, replace the battery immediately.
4 *REPLACE BATTERY*  voice prompt or indicator on key panel flashes.	Very low battery.	• Replace battery immediately.
5 Service indicators  appear on Readiness Display and key panel (CALL SERVICE message *not* displayed).	A fault requiring service.	• Continue to use the AED if it is needed. Contact authorized service personnel as soon as possible to repair the AED.
6 Service indicator on key panel flashing and  CALL SERVICE message appears.	A fault requiring immediate service.	• Turn AED off and on. If the CALL SERVICE message appears again, remove the AED from active service. Immediately contact authorized service personnel to repair the AED.

Observation	Possible Cause	Corrective Action
7 AED displays no messages after you repeatedly press ON/OFF.	Depleted battery. AED needs service.	• Replace the battery immediately. • Contact authorized service personnel.
8 CHARGE REMOVED message appears.	Electrode disconnects from patient or AED.	• Replace electrode and follow AED voice prompts.
	SHOCK button not pressed within 15 seconds.	• Press SHOCK within 15 seconds after the PUSH TO SHOCK message appears.
9 Displayed time is incorrect.	Time is incorrectly set in the AED.	• Change the AED time setting.
10 Date printed on report is incorrect.	Date is incorrectly set in the AED.	• Change the AED date setting.
11 Displayed messages are faint or flicker.	Low battery power. Out of Temperature Range.	• Replace the battery immediately.
12 Voice prompts sound faint or distorted.	Low battery power.	• Replace the battery immediately.
13 AED operates but LCD is blank.	Operating temperature is too low or too high.	• Operate the AED between 0° and +50°C (+32° to +122°F).
	LCD not operating properly.	• Contact authorized service personnel.
14 AED turns off or will not turn on.	Depleted battery.	• Replace the battery immediately.
	Disconnected battery.	• Install battery.

Table 6-2 Troubleshooting During Modem Data Transfer

Observation	Possible Cause	Corrective Action
1 BUSY and WILL RE-DIAL IN XX SECONDS messages.	Destination number is busy, the AED is preparing to retry.	• Wait for the AED to retry the data transfer. • AED will retry up to three times.
2 TRY AGAIN, TO SEND PUSH or CANNOT SEND messages.	Transmission failed.	• AED will retry up to three times.
	Wrong phone number.	• Check the destination phone number and MODEM PHONE NUMBER setup option.
	Cable is not properly connected.	• Check connections.
	Modem is not connected to an analog telephone line.	• Confirm that the telephone line is analog (not digital).
	Incorrect modem selected in Setup menu.	• Check modem selected in SETUP OPTIONS menu.
	Custom Modem Init String is incorrect.	• Check MODEM INIT STRING.
	Dial string for destination site is incorrect.	• Check the AED MODEM PHONE NUMBER setup option.

Observation	Possible Cause	Corrective Action
	Computer power at destination is not on.	• Make sure the computer power is on.
	Computer application program is not ready.	• Make sure the program is ready to receive data.
	Connection failed or is busy. AED has tried to send data three times.	• Resend the data.
3 CONNECT ELECTRODES message.	AED was turned on before modem.	• Turn off the AED for one minute. Then, turn on the modem *before* the AED power and resend the data.
4 LOW BATTERY message or indicators appear on Readiness Display and key panel.	Low battery.	• If using AED, continue to use and replace battery at earliest convenience. Approximately 20% of batttery energy remains. • If AED not is use, replace the battery immediately.
5 *REPLACE BATTERY* voice prompt or indicator on key panel flashes.	Very low battery.	• Replace battery immediately.

Table 6-3 Troubleshooting During Printing

Observation	Possible Cause	Corrective Action
1 Printer does not print.	No printer power.	• Make sure the printer cord is connected. • Make sure the printer switch is on.
	No printer paper.	• Check the printer paper.
	Printer cable not connected.	• Check the printer cable connections.
	Wrong type of printer.	• Check the printer to make sure that it is EPSON ESC/P-compatible.
2 Printed report does not line up properly on paper.	Wrong paper size selected.	• Make sure correct paper size is selected (8 1/2 x 11 or A4) in SETUP OPTIONS menu.
3 CONNECT ELECTRODES message:	The ▶ button was not held down when the AED was turned on.	• Hold down the ▶ button while turning on the AED.
4 LOW BATTERY message or indicators appear on Readiness Display and key panel.	Low battery.	• If using AED, continue to use and replace battery at earliest convenience. Approximately 20% of battery energy remains. • If AED not in use, replace the battery immediately.

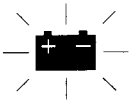
Observation	Possible Cause	Corrective Action
5 *REPLACE BATTERY* voice prompt or indicator on key panel flashes. 	Very low battery.	• Replace battery immediately.

Table 6-4 Troubleshooting During Setup Transfer

Observation	Possible Cause	Corrective Action
Original AED displays CANNOT SEND message.	Setup Transfer Cable is not properly connected.	• Check the connections between the Setup Transfer Cable, the original AED, and the receiving AED.
	Wrong cable is connected.	• Connect the Setup Transfer Cable to the original AED and the receiving AED.
	Receiving AED is not on.	• Make sure the receiving AED is on.
	Receiving AED was turned on with electrodes connected or while AED was connected to computer or modem.	• Turn the receiving AED off and on with the Setup Transfer Cable connected.
	Receiving AED failed to receive transmission.	• Turn the receiving AED off and on with the Setup Transfer Cable connected.

Table 6-5 LIFEPAK 500 AED Screen Messages

Screen Message	Description
ANALYZING NOW	The AED is analyzing the patient ECG rhythm.
ASYSTOLE	The AED has analyzed the patient's ECG and detected persistent asystole.
ASYSTOLE DETECTOR	Setup mode message for asystole time option.
AUDIO RECORDING	Setup mode message for the audio recording option.
AUTO ANALYZE	Setup mode message for auto analyze options.
BATTERY OK	The battery voltage is ok.
BUSY	While attempting to transfer data by modem, the AED detected that the destination phone number was busy.
CALL SERVICE	The AED detected a fault requiring immediate service during self-tests.
CANNOT SEND	The AED could not transfer the setup, print a report, or transfer data through a modem.
CHARGE REMOVED	The SHOCK button has been disarmed.
CHECK FOR PULSE	AED prompt after each standard three-shock sequence or NO SHOCK ADVISED message.
CONNECT ELECTRODES	The AED has detected that the electrodes are disconnected.
CPR TIME XX SEC	Setup mode message for the CPR timer option.
CPSS DURING CPR	Setup mode message for CPSS during CPR option.

Screen Message	Description
DEVICE ID XXXXXXXX	Setup mode message for device ID option.
ENERGY SEQUENCE #2-XXX	Setup mode message for energy sequence option.
IF NO PULSE	AED prompt that follows the CHECK FOR PULSE message.
LOW BATTERY	The battery voltage is low.
MODEM INIT STRING XXXXXXXXXXXXXXXXXXXX	Setup mode message for the modem initialization string option.
MODEM PHONE NUMBER XXXXXXXXXXXXXXXXXXXX	Setup mode message for the modem phone number option.
MODEM SELECTION # XX	Setup mode message. You may select the configuration for one of nine Hayes AT-compatible modems.
MOTION DETECTED	The AED detects motion during ECG analysis, thereby inhibiting analysis.
MOTION DETECTION	Setup mode message for motion detection option.
NO SHOCK ADVISED	The AED has analyzed the patient ECG and detected a nonshockable ECG rhythm.
PUSH ANALYZE	Press ANALYZE to begin ECG analysis.
PUSH TO SHOCK	The AED is fully charged and ready to provide therapy. This is the AED prompt to press SHOCK to discharge.
REPLACE BATTERY	The battery voltage is very low.
SELF-TEST XX.XX	The self-test is being performed and software version xx.xx is installed.
SEND COMPLETE	The AED successfully transferred data.
SENDING	The AED is transferring the setup to another AED.
SENDING XX% COMPLETE	The AED is transferring data by modem or to a printer. The transfer is xx% complete.
SETUP MODE nnnnnnnnnnnnnnnnnn	The AED is in the setup mode. The nnnnnnnnnnnnnnnnnn is the Device Configuration code.
SHOCK ADVISED	The AED has analyzed the patient ECG rhythm and detected a shockable ECG rhythm.
STAND CLEAR	The AED prompt to move everyone away from the patient.
START CPR	The AED prompt that follows the IF NO PULSE message.
STOP MOTION	See MOTION DETECTED.
TEST MODE	The AED has entered the test mode.
TEST OK	The external test load test has been successfully completed.
TO PRINT PUSH ▶	The AED is connected to a printer and ready to print a report.
TO SEND PUSH ▶	The AED is connected to a modem and ready to transfer data.

Screen Message	Description
TRANSFER SETUP TO SEND PUSH ▶	Setup mode message for the Transfer Setup feature.
TRY AGAIN	The AED is ready for you to retry transferring data by modem.
WILL RE-DIAL IN XX SECONDS	While attempting to transfer data by modem, the AED detected that the destination phone number was busy. The AED will try again in xx seconds.

Table 6-6 LIFEPAK 500 AED Voice Prompts

Voice Prompt	Description
ANALYZING NOW, STAND CLEAR	The AED is analyzing the patient ECG rhythm.
ASYSTOLE	The AED has analyzed the patient ECG and detected persistent asystole.
CHECK FOR PULSE	Check the patient for a pulse.
CONNECT ELECTRODES	The AED detects that the electrodes are disconnected.
IF NO PULSE, START CPR	If patient pulse is not present, start CPR.
IF NO PULSE, PUSH ANALYZE	If patient pulse is not present, press ANALYZE.
MOTION DETECTED, STOP MOTION	The AED detects motion during ECG analysis.
NO SHOCK ADVISED	The AED has analyzed the patient ECG and detected a non-shockable ECG rhythm.
PUSH ANALYZE	Press ANALYZE to begin ECG analysis.
REPLACE BATTERY	The battery voltage is low and must be replaced immediately.
SHOCK ADVISED	The AED has analyzed the patient ECG and detected a shockable ECG rhythm.
STAND CLEAR	Move away and do not touch patient.
STAND CLEAR, PUSH TO SHOCK	The AED is fully charged and ready to provide therapy. This is the AED prompt to move everyone away from the patient, then press SHOCK to discharge.

Table 6-7 LIFEPAK 500 AED Event Types[1]

Possible Event Types
Event Log Report
POWER ON
PATIENT CONNECTED
ANALYSIS X
SHOCK X - XXXJ
CPR PROMPT
CHECK PATIENT
CHARGE REMOVED
BATTERY REMOVED
BATTERY REPLACED

Possible Event Types
MOTION DETECTED
ANALYSIS STOPPED
OUT OF EVENT MEMORY
OUT OF ECG MEMORY
OUT OF SCENE AUDIO MEMORY
POWER OFF
Event Log Summary
FIRST ANALYSIS
FIRST SHOCK
SHOCK(S) DELIVERED

[1] These events and all voice prompts may appear in the Event Log Report.

APPENDIX A
SHOCK ADVISORY SYSTEM

This section describes the basic function of the Shock Advisory System (SAS).

OVERVIEW OF THE SHOCK ADVISORY SYSTEM

The Shock Advisory System (SAS) is an ECG analysis system built into the LIFEPAK 500 AED that advises the operator if it detects a shockable or nonshockable rhythm. This system makes it possible for individuals not trained to interpret ECG rhythms to provide potentially-lifesaving therapy to victims of ventricular fibrillation or pulseless ventricular tachycardia. The Shock Advisory System contains the following features:

- Electrode contact determination
- Automated interpretation of the ECG
- Operator control of shock therapy
- Continuous Patient Surveillance System
- Motion detection

Electrode Contact Determination

The patient's transthoracic impedance is measured through the defibrillation electrodes. If the baseline impedance is higher than a maximum limit, it is determined that the electrodes are not in sufficient contact with the patient or not properly connected to the AED. ECG analysis and shock delivery are inhibited. The operator is advised to connect electrodes any time electrode contact is inadequate. If you continue to get a CONNECT ELECTRODES message, remove electrodes and make sure skin is clean and dry. Shave excessive hair and apply a new set of electrodes.

Automated Interpretation of the ECG

The Shock Advisory System is designed to recommend a shock if it detects the following:

- **Ventricular fibrillation** — with a peak-to-peak amplitude of at least 0.08mV
- **Ventricular tachycardia** — defined as having a heart rate of at least 120 beats per minute, QRS width of at least 0.16 seconds, and no apparent P waves.

The Shock Advisory System is designed to recommend no shock for all other ECG rhythms including asystole, pulseless electrical activity, idioventricular rhythms, bradycardia, supraventricular tachycardias, and normal sinus rhythms.

ECG analysis is performed on consecutive 2.7-second segments of ECG. The analysis of two out of three consecutive segments must agree before a decision (SHOCK ADVISED or NO SHOCK ADVISED) is made.

The LIFEPAK 500 AED's SAS performance is summarized in the following table.

Table A LIFEPAK 500 AED SAS Performance Table

Rythm Class	ECG Test[1] Sample Size	Performance Goal	Observed Performance
Shockable: VF	168	>90% sensitivity	LIFEPAK 500 AED meets the AAMI DF39[2] requirements and AHA recommendations[3].
Shockable: VT	65	>75% sensitivity	LIFEPAK 500 AED meets the AAMI DF39 requirements and AHA recommendations.
Nonshockable: NSR	144	>99% specificity for NSR (AHA)	LIFEPAK 500 AED meets the AHA recommendations.
Nonshockable: asystole	43	>95% specificity	LIFEPAK 500 AED meets the AAMI DF39 requirements and AHA recommendations.
Nonshockable: all other rhythms	531	>95% specificity	LIFEPAK 500 AED meets the AAMI DF39 requirements and AHA recommendations.

Rythm Class	ECG Test[1] Sample Size	Performance Goal	Observed Performance
Intermediate: fine VF	29	Report only	89.7% sensitivity.

[1]From Medtronic Physio-Control ECG database. Each sample is run 10 times asynchronously.

[2]Association for the Advancement of Medical Instrumentation. DF39-1993 Standard for Automatic External Defibrillators and Remote-Control Defibrillators. Arlington, VA: AAMI;1993.

[3]Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety. AHA Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. *Circulation*, 1997, Vol. 95, 1677-1682.

VF = ventricular fibrillation
VT= ventricular tachycardia
NSR = normal sinus rhythm

Operator Control of Shock Therapy

The Shock Advisory System causes the AED to charge automatically when it detects the presence of a shockable rhythm. When a shock is advised, the operator remains in control of when the shock is delivered.

Continuous Patient Surveillance System

The Continuous Patient Surveillance System (CPSS) automatically monitors the patient's ECG rhythm for a potentially shockable rhythm while the electrodes are attached and the AED is turned on. CPSS is not active during ECG analysis.

Motion detection is not active during the CPSS. Therefore, there is a chance that motion distortion in the ECG rhythm may be interpreted by CPSS as a potentially shockable rhythm.

Motion Detection

The Shock Advisory System detects patient motion independent of ECG analysis. A motion detector is designed into the LIFEPAK 500 AED. MOTION DETECTION can be configured in the setup mode to be ON or OFF.

Motion can be caused by CPR, rescuer movement, patient movement, vehicle movement, or other causes. If variations in the transthoracic impedance signal exceed a maximum limit, it is determined that patient motion of some kind is present. ECG analysis is inhibited until the motion ceases. The operator is advised any time motion is detected during an analysis by a displayed message, a voice prompt, and an audible alert. If the motion does not cease within 20 seconds, analysis attempts will stop until the operator presses the ANALYZE button again. For LIFEPAK 500 AEDs without an ANALYZE button, analysis restarts automatically. If the motion does cease within 20 seconds, ECG analysis proceeds automatically.

There are two reasons why ECG analysis is inhibited when motion is detected:

1 Such motion may cause artifact in the ECG signal. This artifact can cause a nonshockable ECG rhythm to look like a shockable rhythm. For example, chest compressions during asystole can look like shockable ventricular tachycardia. Artifact can also cause a shockable ECG rhythm to look like a nonshockable rhythm. For example, chest compressions during ventricular fibrillation can look like an organized and, therefore, nonshockable rhythm.

2 The motion may be caused by a rescuer's interventions. To reduce the risk of inadvertently shocking a rescuer, the motion alert prompts the rescuer to move away from the patient. This will stop the motion and ECG analysis will proceed.

APPENDIX B
LIFEPAK 500 OPERATOR'S CHECKLIST

LIFEPAK® 500 automated external defibrillator OPERATOR'S CHECKLIST

Unit Serial No.:_____
Location:_____

This is a suggested checklist for inspecting and checking this device on a daily basis and after each use. You may also consult JAMA, August 22/29, 1990, Vol. 264, No. 8, Table 3 for the Defibrillator Working Group's automated defibrillator checklist.

This form may be reproduced.

Medtronic PHYSIO-CONTROL

Instruction	Recommended Corrective Action	Date / Initials

Insert a ✔ in the box after completing each instruction.

1 Examine the AED case, connector, and battery well for:

Foreign substances	Clean the device.
Damage or cracks	Contact authorized service personnel.

2 Examine the battery pins for bending or discoloration. Discard and replace battery.

3 Check expiration date on batteries and therapy electrodes. Replace if expired.

4 Examine the accessory cables for cracked, damaged, broken, or bent connectors or wires. Replace damaged or broken parts.

5 With the battery installed, press On/Off to turn on the AED and look for:

Self-test messages	If absent, contact authorized service personnel.
Momentary illumination of each LED and all LCD segments	If absent, contact authorized service personnel to repair or replace parts.
BATTERY LOW or REPLACE BATTERY SELF-TEST XX.XX message	Replace the battery immediately.
Service indicator or CALL SERVICE message	Contact authorized service personnel.

APPENDIX C
FAST-PATCH DEFIBRILLATION CABLE INSTRUCTIONS FOR USE

FAST-PATCH® defibrillation cable
for LIFEPAK® 500 automated external defibrillator

Instructions for Use

Introduction

To use FAST-PATCH disposable defibrillation/ ECG electrodes, the LIFEPAK 500 automated external defibrillator (AED) requires this FAST-PATCH defibrillation cable (see Figure 1).

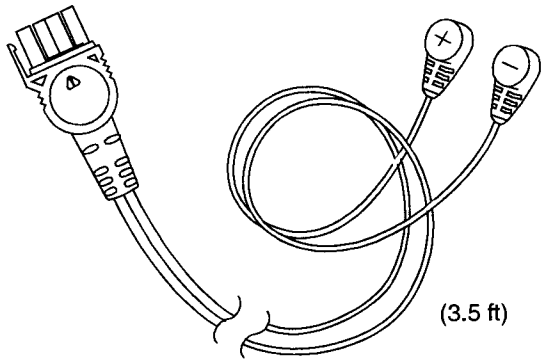


Figure 1 FAST-PATCH defibrillation cable for the LIFEPAK 500 AED

WARNING!
Inability to deliver therapy.
Only FAST-PATCH electrodes can be used with the FAST-PATCH defibrillation cable.

CAUTION!
Possible equipment damage.
To prevent water or foreign substance contamination, keep the protective cover for the AED connector closed or the defibrillation cable inserted when the device is not in use.

Symbols

The following symbols appear on the defibrillation cable:

⚠	Attention, consult accompanying documents
+	Positive terminal
–	Negative terminal

Important

Operators should be thoroughly familiar with the LIFEPAK 500 AED Operating Instructions and the FAST-PATCH disposable defibrillation/ECG electrode Operating Instructions before using this defibrillation cable.

Cable Attachment

A lanyard is provided to help prevent loss of the defibrillation cable.

To attach the lanyard:

1 Loop the lanyard around the AED connector-end of the cable (see Figure 2).
2 Loop the defibrillation cable through the lanyard and around the AED handle (see Figure 2).
3 Insert the cable firmly into the AED until a positive stop is felt (see Figure 3).

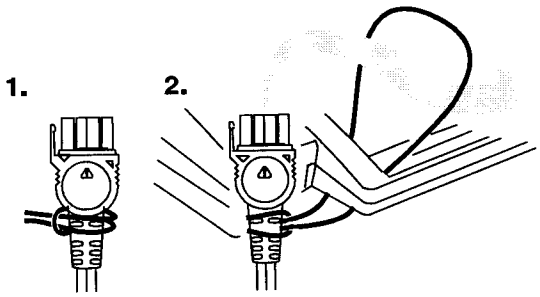


Figure 2 Attaching lanyard

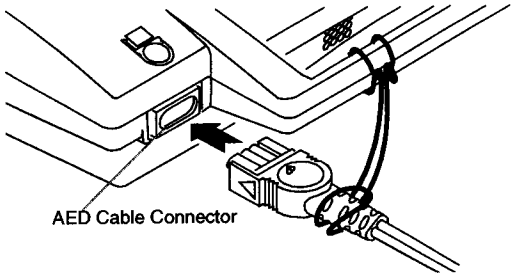


Figure 3 Inserting defibrillation cable into AED

Remove the defibrillation cable for data transfer by pulling the connector straight out. Reconnect the defibrillation cable to the AED after data transfer, or close the protective cover on the AED cable connector.

Connecting to FAST-PATCH defibrillation/ECG electrodes

Properly connect the defibrillation cable to the electrodes to help ensure energy delivery (see Figure 4).

- Attach the cable to the electrode post before attaching electrodes to the patient.
- Support the electrode post under the electrode when attaching the cable to the electrode.
- Firmly press the snap connector onto the electrode post until a click is heard or felt.
- Confirm a secure connection of the cable to the electrode before proceeding with therapy by pulling up gently on the snap connector.

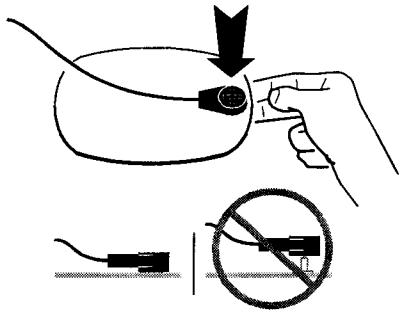


Figure 4 Connecting to FAST-PATCH defibrillation/ECG electrodes

Note: If reattaching an electrode that is already on the patient, lift the adhesive edge under the electrode post slightly and place your finger under the post. Connect the cable as described above.

Disconnecting from disposable electrodes

Disconnect the defibrillation cable from the electrode by pulling the snap connector straight up and off the post to avoid damage to the cable or the post (see Figure 5).

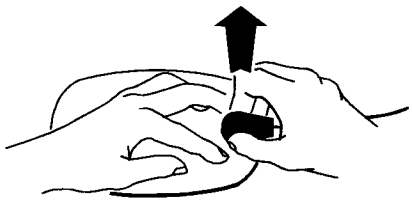


Figure 5 Disconnecting from electrodes

Colors and Symbols

The defibrillation cable has colors and symbols on the snap connectors consistent with industry standards:

- AHA standards - red and white
- IEC standards - green and red

The snap connectors are labeled "+" (apex) and "–" (sternum). Refer to the FAST-PATCH electrode operating instructions for electrode placement information.

Cleaning and Testing

To clean the FAST-PATCH defibrillation cable and snap connectors, wipe the surface with any one of the following:

- Mild soap and water
- Isopropyl alcohol
- Peracetic (peroxide) acid solutions
- Quaternary ammonium compounds

Contact local infection control resources for specific questions regarding cleaning procedures or cleaning agents available in your area.

- Do not immerse or soak the defibrillation cable
- Do not use bleach or bleach dilution
- Do not steam or gas sterilize

Inspect and test the defibrillation cable on a routine basis. Inspection and testing will help ensure that the equipment is in good operating condition and is ready for use when needed. Use the Physio-Control Patient Simulator to test the defibrillation cable.

During inspection or testing, if any discrepancy is detected with the defibrillation cable, remove the defibrillation cable from service and immediately contact a qualified service representative.

Ordering Information

Contact your local Physio-Control sales or service office to order parts. In the USA, call the Physio-Control PARTSLINE™ at 1.800.442.1142.

- FAST-PATCH defibrillation cable for LIFEPAK 500 AED (PN 3010493)
- FAST-PATCH disposable defibrillation/ECG electrodes (PN 3006292)
- PHYSIO-CONTROL Patient Simulator (PN 803499)

APPENDIX D
QUIK-COMBO DEFIBRILLATION CABLE INSTRUCTIONS FOR USE

QUIK-COMBO™ defibrillation cable
for LIFEPAK® 500 automated external defibrillator

Instructions for Use

Introduction

If using standard QUIK-COMBO pacing/ defibrillation/ECG electrodes (PN 806086) with the LIFEPAK 500 automated external defibrillator (AED), use the QUIK-COMBO defibrillation cable (PN 3011215) for additional length (see Figure 1).

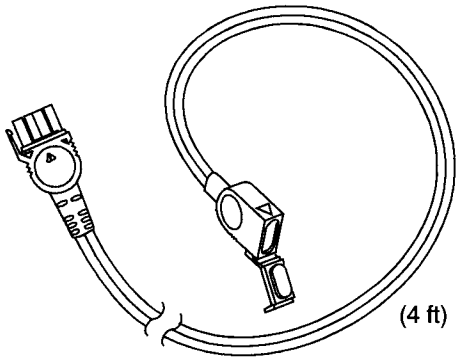


Figure 1 QUIK-COMBO defibrillation cable for the LIFEPAK 500 AED

CAUTION!

Possible equipment damage.

To prevent water or foreign substance contamination, keep the protective cover for the AED connector closed or the defibrillation cable inserted when the device is not in use. Always keep the defibrillation cable protective cover closed when the cable is not in use.

Symbols

The following symbols appear on the defibrillation cable:

⚠ Attention, consult accompanying documents

Important

Operators should be thoroughly familiar with the LIFEPAK 500 AED Operating Instructions and the QUIK-COMBO pacing/defibrillation/ECG electrode Operating Instructions before using this defibrillation cable.

Cable Attachment

A lanyard is provided to help prevent loss of the defibrillation cable.

To attach the lanyard:

1 Loop the lanyard around the AED connector-end of the cable (see Figure 2A).

2 Loop the lanyard around the handle of the AED and feed the defibrillation cable through the loop (see Figure 2B).

3 Insert the cable firmly into the AED until a positive stop is felt (see Figure 3).

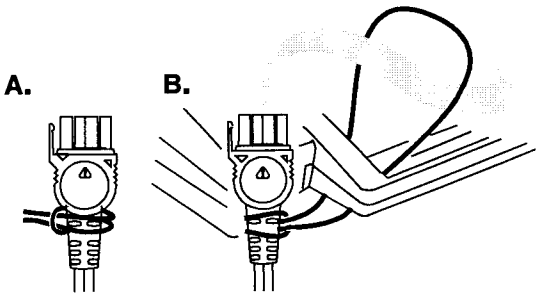


Figure 2 Attaching lanyard

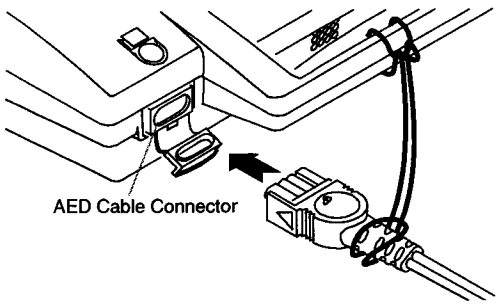


Figure 3 Inserting defibrillation cable into AED

Remove the defibrillation cable for data transfer by pulling the connector straight out. Reconnect the defibrillation cable to the AED after data transfer, or close the protective cover on the AED cable connector.

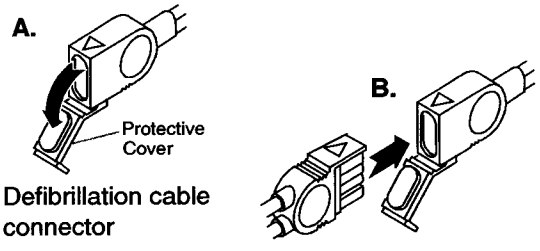
After using the defibrillation cable, always close its protective cover.

Connecting to QUIK-COMBO pacing/ defibrillation/ECG electrodes

Properly connect the defibrillation cable to the electrodes to help ensure energy delivery (see Figure 4).

1 Open the protective cover on the defibrillation cable connector.

2 Insert the QUIK-COMBO electrode connector into the defibrillation cable connector by aligning the arrows on the connectors and pressing the connectors firmly together for proper attachment.



Defibrillation cable connector

QUIK-COMBO electrode connector

Figure 4 Connecting QUIK-COMBO electrodes

Instructions for Use (continued)

Cleaning and Testing

To clean the QUIK-COMBO defibrillation cable, wipe the surface with any one of the following:

- Mild soap and water
- Isopropyl alcohol
- Peracetic (peroxide) acid solutions
- Quaternary ammonium compounds

Contact local infection control resources for specific questions regarding cleaning procedures or cleaning agents available in your area.

- Do not immerse or soak the defibrillation cable.
- Do not use bleach or bleach dilution.
- Do not steam or gas sterilize.

Inspect and test the defibrillation cable on a routine basis. Inspection and testing will help ensure that the equipment is in good operating condition and is ready for use when needed. Use the QUIK-COMBO Patient Simulator to test the defibrillation cable.

During inspection or testing, if any discrepancy is detected with the defibrillation cable, remove the defibrillation cable from use and immediately contact a qualified service representative.

Recycling Information

Recycle the device at the end of its useful life.

Preparation

The device should be clean and contaminant-free prior to being recycled.

Recycling Assistance

The device should be recycled according to national and local regulations. Contact your local Medtronic Physio-Control representative for assistance.

Recycling of Disposable Electrodes

After disposable electrodes are used, follow your local clinical procedures for recycling.

Packaging

Packaging should be recycled according to national and local regulations.

Ordering Information

Contact your local Medtronic Physio-Control sales or service office to order parts. In the USA, call the Medtronic Physio-Control PARTSLINE™ at 1.800.442.1142.

- QUIK-COMBO defibrillation cable kit for LIFEPAK 500 AED (PN 3011215)
- QUIK-COMBO Patient Simulator (PN 803499-09)
- QUIK-COMBO pacing/defibrillation/ECG electrodes (2 ft lead wire) (PN 806086)
- QUIK-COMBO LLW pacing/defibrillation/ECG electrodes (3.5 ft lead wire) (PN 3008826)
- QUIK-COMBO pacing/defibrillation/ECG electrodes with REDI-PAK preconnect system (PN 3008497)